# EXHIBIT D

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

AT CHARLESTON

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| JO HUSKEY AND ALLEN HUSKEY, | : | |
| Plaintiffs, | : | CASE NUMBER |
| v. | : | 2:12-cv-05201 |
| ETHICON, INC., ET AL., | : | |
| Defendants. | : | |

TRANSCRIPT OF TRIAL - DAY TWO

AUGUST 25, 2014

BEFORE THE HONORABLE **JOSEPH R. GOODWIN,**

UNITED STATES DISTRICT JUDGE

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# I N D E X

PROCEEDINGS had before The Honorable Joseph R. Goodwin, Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on August 25, 2014, at 9:08 a.m., as follows:

(The jury entered the courtroom at 9:08 a.m.)

THE COURT: Good morning.

THE DEPUTY CLERK: The matter before the Court is *Jo Huskey, et al. versus Ethicon, Inc., et al.*, Civil Action Number 2:12-cv-5201.

THE COURT: Are the plaintiffs ready to proceed?

MR. WALLACE: Yes, we are, Your Honor.

THE COURT: Defendants ready to proceed?

MS. JONES: We are, Your Honor.

THE COURT: Ladies and gentlemen of the jury, I apologize for the late start. I can tell you it wasn't my fault. It won't happen again.

I trust you had a nice weekend. We're now ready to begin the trial of this case. As I mentioned on Friday, it will begin with an opening statement by the plaintiffs, then response to that by the defendants.

After that, the plaintiffs, since they have the burden of proof, will put on their evidence. After that, the defendants may put on their evidence. After that, plaintiffs may have rebuttal. And after that, the lawyers will argue their case. And I'll give you instructions on the law, and

then you'll deliberate and decide the case.

The important thing to remember is keep an open mind throughout the process. Do not make up your mind until you've heard all of the evidence and my instructions on the law. Opening statements are meant to be a roadmap or a guide as to what each side expects the evidence to prove. Lawyers are always tempted to try to argue their case a little bit in their opening statement. That's not proper. If there's an objection, then there's argument, I'll simply sustain the objection, you ignore that part.

Are you ready? You can bring your bottle of water, if you haven't already, and feel free to do that. If you need a break at any time before our normal 10:30 break, hold up your hand and we'll take a five-minute break.

Are the parties ready?

MR. WALLACE: Yes, Your Honor.

THE COURT: All right. Who will open for the plaintiff?

MR. WALLACE: Edward Wallace, Your Honor.

THE COURT: All right.

MR. WALLACE: May I proceed?

THE COURT: You may proceed, sir.

MR. WALLACE: Thank you.

Good morning. I got to meet you on Friday and you're going to get to meet my clients today.

I'm going to get right to it. That's Jo and Allen Huskey right there. Jo and Allen, could you stand up? And you're going to hear from them later on in the trial.

And this is my chance to talk to you to outline the evidence, as the judge just discussed. What I'm going to be doing, you have monitors in front of you, I've get some photos and some slides and some documents that I'm going to try to use to outline the evidence. There's going to be a lot of medical terminology. Some of you may be very familiar with it; some of you may not. I may mispronounce the names.

The good news is that you're going to hear from medical witnesses who will help us explain these issues to you. But I want to try to put all of this in context, so I'm going to be going through some of the slides today. I'm going to be talking to you. I have a board here. My colleague, Tim Jackson, is going to be putting that board up there, and sometimes as I talk, he'll put some information on the board to help you orient some of the dates, because you're going to see a lot of slides here with a lot of dates and a lot of information. And what we want to do is this evidence is going to come out over the course of the trial. And so what we're going to do with the boards is try to sort of help place it in time of where it came, when it comes to the before and after picture. Okay?

So I'm going to get started.

The evidence is going to show, ladies and gentlemen, that Jo Huskey, my client, was implanted with a device on February 23, 2011. That's a key date in this case. That device was designed, it was made, and it was sold by Ethicon and Johnson & Johnson, the defendants in this case. There's no dispute about that. The device, as you heard Friday, is called the TVT-O. It stands for "transvaginal obturator," and you're going to hear a lot of information about the obturator space and the transvaginal approach. And I'll explain some of that today, but, again, you're also going to hear from medical witnesses.

This device, the TVT-O, was designed and marketed to treat a condition called "stress urinary incontinence." Again, I'm going to talk a little bit about that today. But you'll also hear from medical witnesses about that.

Another important fact that you should know right up front, Ethicon and Johnson & Johnson designed this very device so that it would remain inside of a woman's pelvic cavity forever. There's no dispute about that. It's a permanent implant.

There are certain fundamental safety principles that apply here that you should be aware of. The first is that a medical device manufacturer must put patient safety first. That's the number one priority. There should be no questions about that, no excuses.

The second is that a medical device manufacturer must make sure that its products are reasonably safe for their intended use.

And finally, third, a medical device manufacturer must provide adequate warnings of risk. Those are three safety principles that we're going to talk about today, hopefully, in some order that I can get through.

And we allege here, as you can see on the screen, that Ethicon failed to follow these recognized safety principles. The evidence is going to show, ladies and gentlemen, that Ethicon knew about complications, it knew that these complications were serious. In fact, you're going to learn through the evidence that's introduced in this case that Ethicon knew that some of these events were life altering, life altering.

You're also going to learn and the evidence will show that Ethicon made a choice not to disclose this information in its instructions for use and not to disclose this information in other ways. And you're going to hear evidence in this case, some of which I'm going to outline today, and you heard Friday about a reasonable company. We allege by failing to disclose, when it knew the complications were serious, it knew the complications were life altering, evidence that you will see, that Ethicon failed to act as a reasonable person or company. That's one of our claims.

And you're going to hear from several witnesses in this case. Some will sit in that witness box and testify under oath. There will also be people that testify by video deposition. Some of you may know what a deposition is. It's when you're sworn under oath to give testimony. Some of that testimony is sometimes recorded. The good news is that you'll be able to watch it right there. We ask that you watch it just as if they were in this courtroom.

One other thing that I want to point out. We submit to you that the evidence you're going to see as to the question of whether or not this device was defective is an overwhelming yes. We want to make that as clear as daylight. But as a brief reminder, this is a civil case. And our burden to prove our claims is by a preponderance of the evidence, meaning that we have to prove our claims are more probably true than not true. (Indicating.)

Why do I say this? It's pretty simple. Jo Huskey and Allen Huskey have come too far and too long to get anything other than a fair shake and a fair trial. And that goes for both sides, absolutely. But this is the only place and the only chance that Jo and Allen Huskey will be heard.

One other thing. There's going to be a lot of medical witnesses. There are no claims, no claims whatsoever, against the doctor that implanted this device. Nor are there any claims by us or by Ethicon in that regard, by the way,

against this doctor. There are also no claims against any other doctor that provided the follow-up care to Jo Huskey. So remember that as you listen to the evidence in this case.

Let me go back to the medical condition. That's a slide, a photo, of normal pelvic anatomy, and you'll see there on the right side of the screen in front of you, you'll see the rectum, the back part of the patient, and you'll see in the front of that, the vagina, and right in front of the vagina, you'll see the urethra. What's important is that you're going to see different views of this same anatomy, so I'm trying to help you keep it in context as you sit through the evidence in this case. Right above the urethra sits the bladder, next to the pubic bone.

Now, let's talk about SUI for a moment. The most common cause of stress urinary continence -- incontinence is the weakening of some of the tissues and muscles in the pelvis. It can happen with aging, it can happen as a result of childbirth and other causes. It's a relatively common condition. You're going to learn this in this trial, that it affects somewhere around 30 percent of women who have SUI. Some have it more than others. Some have it with just coughing and exercising and sneezing. Some people have it much more severe than that.

And when that happens -- let me show you the next slide. That's the effect of SUI. What happens is that the

urethra that I just showed you falls from its proper position and so that the bladder can then begin to leak involuntarily.

One thing that's real clear, or should be real clear, hopefully, by the close of this case, and the evidence will show this: Ethicon designed this TVT-O device to support those weak tissues. Ethicon designed this device for women that were postmenopausal, premenopausal, that had leaking tissues. That's what this device was for. That was their market.

You have to -- you have to understand as this case goes along that we'll be talking about some embarrassing conditions. Certainly, perhaps embarrassing or uncomfortable for Jo and Allen Huskey and some of us or maybe all of us. And, but it's important that we talk about this stuff because we have to give this case the dignity that it deserves, so when some of us may say something that's embarrassing or you see something that might be uncomfortable, just rest assured we're trying to do the right thing.

And it's important for you to know that SUI does not adversely affect the women's health. As I said, it can be embarrassing, absolutely. It can sometimes be uncomfortable.

Let's move on and talk about the TVT-O device. What is the TVT Obturator Sling? The TVT-O actually comes in what's called a kit. It has different pieces that are inside of this kit. It actually comes in a box, and I'm going to

show you the box right now because this is what I'm referring to when I talk about the kit. Okay? And I'll get more into it than that. But I want to talk to you about some key pieces that come inside that kit because this is the product.

That's a picture of some of the devices that I want to talk about in this case and outline some of the evidence that you're going to see here. You see there's a strip of mesh and what are called trocars which are the surgical devices to deliver the mesh. You see a winged guide. And the evidence, as I said, will show that Mrs. Huskey had this mesh, the TVT-O mesh, put inside of her on February 23, 2011. That's actually what is left in the body to try to treat SUI.

These are the trocars in my hand, ladies and gentlemen, that are used to deliver the mesh. What I've got in front of me is the actual mesh, and it's actually just a strip of plastic. It's made out of a product called "polypropylene." Some of you may have heard of polypropylene before. It's just a manmade chemical that's made by an oil and gas company that is processed and then eventually becomes the mesh. It's obviously a little bit more involved than that, but this is really just a polypropylene mesh, and this is what's left behind in the body, without the sheath that is over it.

And this is delivered through what's called the transobturator space. I'm going to try to walk through just a

little bit about how this goes in, okay, but, again, you're going to hear from medical witnesses on this.

I'll just try to explain. The TVT-O mesh, it's actually inserted underneath the urethra to hold it in its proper place. And to do that, a doctor actually makes a cut in the wall of the vagina and actually inserts the mesh transvaginally, so that's part of the reason why it's called the "TVT." It sort of means what it says, the O stands for "obturator" because this mesh eventually goes into the obturator foramen and out through the inner thigh and groin. And these trocars are used to push the mesh through tunnels when it goes through transvaginally up through the obturator foramen.

Let me just go ahead and get to the slide so maybe we can understand it together. But I want to tell you something before we get there.

This obturator space that I've been talking about, again, you're going to hear evidence in this case, this is the testimony of the doctor that tried to take the mesh out of Mrs. Huskey.

And there is some testimony from his deposition, it's going to be played by video in this case, and he's asked about his ability to remove the entire mesh.

And he's asked, "Can you explain why all of the mesh could not be removed?"

He says he's never done that before. You're going to learn that he's not alone. Operating in the transobturator space is something very few surgeons in the United States, let alone the world, would attempt to do. The implant through the transobturator space is extremely problematic if there is a complication. That's one of our claims in this case. If there's a complication -- remember how I said it was a permanent implant? The evidence is going to show that it's extremely problematic to get this mesh out. The evidence will also show that Ethicon had no prior experiencing -- experience developing an SUI device to be implanted in the transobturator space. That is an important piece of evidence that you should consider in this case.

The third piece of the kit, besides the trocars and the mesh, that I want to talk about, are the instructions for use.

By the way, before I do that, why don't I just talk a little bit about, that's a better picture of how the TVT-O lays inside the woman's pelvis. If you remember that view that I showed you, I showed you the rectum from the side, on the right-hand side, the vagina and then the urethra, and I said that the TVT-O sits underneath the urethra. This space out here, this here is the obturator foramen and this mesh actually sits in there.

That's the obturator membrane that you're going to

hear so much about, and you're going to hear it from people that are much more able to talk about it than I can.

But remember, TVT-O means "transvaginal tape obturator."

That's actually an animation from Ethicon of how the trocars are used to insert the tape. You can see that the winged guide is being -- the trocars are literally going transvaginally into the obturator foramen and creating these little tunnels, and so the mesh follows along the tunnels which are essentially wounds, and that mesh is supposed to lay there forever.

Like I said, the next thing I want to talk about is the instructions for use. That's a piece of information that comes in this kit. Okay? And that tells the physician three important things:

It tells the physician how to implant the product, and if you look here you see contraindications. You may have seen that on a label before, on other medical products. It tells the doctor in these kinds of cases who is not an appropriate candidate -- that's going to be very important in this case -- who is and who isn't an appropriate candidate for the TVT-O device.

What else is supposed to be in the instructions for use? Evidence you're going to hear in this case, we're going to talk about adverse reactions, risks and warnings. This is

supposed to tell the physician about the complications or adverse events that may be associated with the use of the TVT-O device.

And you will learn, and I'll go right to it, you will learn from evidence in this case that Ethicon agrees, Ethicon agrees that the surgeon should be able to solely rely on the IFU, absolutely, to get risks and warnings and information. This is a way that Ethicon can meet its obligation to be a reasonably careful company. And one of our claims is this IFU and this warnings information was inadequate and not provided.

This is -- and let me just back up for a second and talk about the fact that, of course, the doctor, once the doctor receives this information, is in the important position of then talking to the patient about the risks. But about the true risks because, as you're going to learn, and you're going to know by the end of this case and the evidence will show, that Ethicon is in the position and has the obligation to know what's going on with its product, and if it knows what's going on with its product, you're going to hear evidence that even Ethicon agrees that it should be in the instructions for use.

Right there. That is an Ethicon medical director, a higher-up at Ethicon. His deposition was taken, and he was asked: "Would you agree with me, Dr. Robinson, that the warnings and adverse reactions section should include all significant risks and complications related to the use of the

TVT?

"Well, those deemed significant."

And I submit to you that the evidence will show that there were significant complications that were not part of the IFU.

He's also asked: "And it should also include risks and complications related to the implementation of the mesh, right?

"Well, that's both the device and the procedure, yes."

Because this comes in a kit, and as you're going to learn and hear testimony in the case, that this procedure, you can't just do this procedure on a whim. They provide very specific instructions for use that you're supposed to follow. You're going to learn about something called the inside-out approach and other very specific directions, and that are part of the design -- part of the design, ladies and gentlemen, that come with this unique TVT-O device that raise unique complications. So it's the procedure and the device.

Let me talk to you, because you're going to hear information perhaps about other mesh. Let me just give you a brief history lesson.

1974, I believe that was when President Nixon was impeached, 40 years ago. The old construction Prolene mesh was developed. 1974. That was not for SUI. That was for a

different application entirely and that was made basically in large sheets. Okay?

It wasn't until 1998 that Ethicon got into the market of treating SUI with these mesh sticks, and it made what it called the TVT. Okay? And the TVT, as you see here in 1998 and you're going to learn, was inserted much differently. It was also cut much differently than the device that was put in my client. It's a different product, inserted a different way.

You're going to learn that in 2003, Ethicon decided to launch the TVT-O with no prior clinical trials. This new way of putting this in, through an entirely new part of the body, where surgeons normally don't even operate. That's what the evidence will show. They decided to launch this device in 2003. That device, by the way, in 2003, that first TVT-O device, was cut very much the same way as that 1998 TVT. It was cut mechanically, with a machine.

It isn't until 2007 that Ethicon begins what is called laser-cut mesh in the TVT-O. Let me make something absolutely clear when you hear about lots of other different products. The evidence will show that my client received a TVT-O laser-cut mesh which first came to market in 2007. So when you hear about long-term data, keep that date in mind.

As you know, she received the TVT-O laser-cut mesh on February 23, 2011. And you're going to hear evidence in this

case that Ethicon had safety signals in front of it, and it failed to stop when it saw those signals, that it moved ahead, that it made decision -- made decisions at the highest levels of the company. The Board of Directors was making decisions about what was going on with this device. So what did Ethicon do wrong?

Well, you're going to learn that Ethicon, prior to the TVT-O device, never did a randomized control trial with a primary outcome safety prior to launching. What is a randomized control trial? Some of you may know this. It's a clinical trial that you can use in a controlled clinical setting to assess how your product is performing. But what are called "endpoints," what you're actually looking at in this study, is really important because you can be comparing one product to another and say, "Well, my product works just as good as the other one. But that's not at issue here. Whether my product works as good as the other one is not at issue here.

The question is about safety. Are you putting safety first?

Again, what did Ethicon do wrong? We allege that Ethicon rushed the TVT-O to market without the proper clinical data, especially safety data. We allege that Ethicon converted from mechanical-cut mesh to laser-cut mesh without any clinical tests or long-term data.

Important claim. Ethicon knew -- we allege that they knew that the TVT-O was causing serious problems for women but did nothing. And we allege that Ethicon did not disclose those complications to doctors and to the public.

What is the result? What is the result, ladies and gentlemen? Why is the TVT-O defective? It's the wrong material. You're going to learn about polypropylene in the pelvis. You're going to learn that it was in the wrong space. It was inserted through the obturator space. You're going to learn that it was the wrong approach. It came with unique risks that Ethicon knew about right after this product launched. It was the wrong amount. Too much mesh equals increased complications, and we allege that Ethicon knew about it and sat on this information for years. It was the wrong product.

Now, there are lots of other choices out there, and you're going to learn today, as I speak to you, about some of these other choices. And let's -- to do that, let's go back to that first safety principle. A medical device manufacturer must put the safety of patients first. What did we allege? We alleged that Ethicon rushed this product to market.

What do I mean by that? Well, in 1998 when Ethicon first began selling this TVT, the evidence is going to show, as you know, that it was a completely different product. What started happening after a few years was that Ethicon was

losing market share. Ethicon, the evidence will show, was losing market share quickly. And Ethicon wanted to do something quickly to change that. They wanted to try to recover that market share.

They did do that in the sense that they rushed this product to market in record time to attempt to recover that market share. Right in front of me -- and I'm going to go up to the board so I can actually read it -- this is talking about the TVT-O. This is exhibits -- or an exhibit that you'll see in the case, and it talks about why the TVT-O was actually created.

It was created in response to what? That's evidence you should consider. What was it created in response to? It was created in response to the fact that "They're rapidly stealing our TVT retropubic sales at an alarming rate." They originally estimated that the TVT-O would take 24 months to launch. They did it in nine months, a record for the company. A record for Ethicon.

What else? This is other information that you will see in this case. "To protect our market share, we need to be ready to launch. So the development process should not require clinicals. I understand that the Gynecare Board made the decision that clinicals will not be required for Mulberry." That's the TVT.

The Gynecare Board, ladies and gentlemen, this is the

higher-ups at Ethicon that are involved in these decisions, the rationale, the rationale, was to defend their sales. But let me make something very, very clear. I'm not sitting up here complaining that it's wrong to make money. Competing is not wrong. Developing products is not wrong. There's nothing wrong with that. But when you prioritize patient safety, that first safety principle that we talked about, we allege in this case that it was wrong and it had consequences.

The evidence will show that Ethicon decided to launch first and worry about problems later. What am I talking about? Let's move on to our next safety principle: "A medical device manufacturer must make sure that its products are reasonably safe." I just told you about the evidence showing that Ethicon would launch first and worry about problems later. You're going to see evidence in this case, remember that timeline that I showed you, that they released in late 2003. In early 2004, March of 2004, there is a secret meeting with the inventor of the TVT-O. Why did they have this meeting? The evidence will show, ladies and gentlemen, that the co- -- the coinventor of the TVT-O met with Ethicon because women were experiencing pain because of this technique, because of this unique TVT-O. They were discussing ways, you're going to learn, in March of 2004, how to modify the TVT-O in an attempt to reduce that pain.

That's actually a document, the Professor de Leval is

actually one of the co-inventors of the product, you'll see that's dated March 29, 2004, and what is he talking about? He's talking about reducing the tape. He's talking about removal of the segment of the tape that passes through the adductor muscles. They are concerned at this point about pain that is being caused to women early on after the launch of this device. You will learn that changes like this were not made for years, for over six years.

In 2009, two years -- two years, ladies and gentlemen, the evidence is going to show, two years before my client gets implanted with the TVT-O device, there is a meeting with an Ethicon medical director and the co-inventors of the TVT-O, Dr. de Leval and Dr. Waltregny. And at that meeting, they again discuss their concerns. Because of what? This is a memo, a report of this meeting. "That the foreign body reaction of the mesh and the trajectory outside the obturator membrane plays a role in the development of pain."

Remember what I said to you about the obturator space. This is a report of a meeting two years before my client was implanted with mesh.

The evidence will show that they were still talking about design changes to reduce pain years later and well in advance of my client being implanted with this device.

What else is important about this? The second source of pain comes from the presence of tape in the adductors.

This is of specific importance in young, active and/or sportive patients. That's what's going on two years before my client gets this device. The evidence will show that no one, doctors, were not informed of this, of these concerns. The IFU was not updated.

And when we're talking about the obturator space, you're going to learn about the foreign body response. I'm just going to switch gears for just a second and talk about the TVT-O and the concerns that they talked about in this obturator membrane where very few surgeons will go, this TVT-O is now reacting to the tissue in that space and the vaginal tissue is now reacting to the polypropylene, causing the problems in patients. That's what the evidence is going to show.

This is the deposition testimony of Dr. Gretchen Byrkit, and she's asked about active patients. And you're going to learn that Jo was a physical therapist assistant and was quite active. She went up to eight miles a day on her elliptical. Dr. Byrkit testified in this case. She's going to be seen in this courtroom by video deposition. She's asked: "So as far as the TVT-O is concerned, an active patient, somebody who is, say, a water aerobics instructor or somebody who does physical therapy, were they contraindicated for the TVT-O procedure?

"Not to my knowledge."

Remember when I showed you the IFU, which will come into evidence in this case? That was not a contraindication.

She's asked: "If you had been told that it shouldn't be implanted in women who are active, actively exercising, fit women, if you had been told that it shouldn't be implanted in those women, would you still have implanted it in Jo Huskey?

"I don't think I would."

Again, competing is not wrong. But putting patient safety first has to be a priority.

Laser-cut mesh, we've talked a little bit about it. You'll see here that, again, this is another attempt to maintain market share. Again, there's nothing with trying to maintain market share. But they decide not to do -- to seek clinical data on it.

And this is an e-mail from Allison London Brown, an employee of Ethicon, and she is recommending that they need clinical data on the laser-cut mesh that is put in my client, prior to launch.

The evidence will show that this did not happen. No clinical data. And what are they saying about how the laser-cut compares to that mechanical-cut that came out in 2003? Inability to claim equivalence. They're ignoring -- the evidence will show that they ignored concerns within the company that clinical data was needed before this was launched.

This was the wrong material and the wrong place. Let's talk about a concept called "degradation." I told you a little bit about the foreign body reaction and you saw that never-ending cycle where the polypropylene reacts to the body and the body reacts to the polypropylene. You're going to hear a lot about that. Ethicon found degradation going back to the 1980s. There were researchers that were starting to find degradation in explanted material from patients, 2009, 2013.

Again, I talked to you about the fact that this is plastic. This is a manmade chemical. You're going to learn that this manmade chemical in the pelvis can break down, it can become brittle, it can curl, it can shape, it can deform. And you're going to -- by the way, you're going to hear that polypropylene is used elsewhere in parts of the body and that it's in sutures and that it's a used in many, many other places in the body.

Again, I want to make one thing clear. This case is not about sutures. This case is about mesh, which is many, many, many times more polypropylene than a plain suture. Polypropylene is this -- woven together to form this mesh. It grows into the body quite differently and it's quite a different reaction and you're going to learn about it.

And you will hear that experts in the scientific field have long accepted that polypropylene is unstable and

can be brittle.

And you're going to hear that degradation, polypropylene can cause this response in the human body. The mesh in the pelvis can incite what is called "chronic inflammation, chronic foreign body reaction and extensive scarring." And it can cause serious issues with pain. These can cause serious problems with women, sometimes called "chronic pain syndrome."

Another problem is that when the mesh degrades, it can become brittle, and you're actually going to hear from physicians that try to remove this and as they take it out, it begins to break apart.

So if you're going to use mesh, you should really only use it where it's needed, because when you incite more of a foreign body response, the evidence is going to show you're just asking for problems.

And you're going to learn, the evidence is going to show, that what was happening, these are -- let me just step over here and just explain this. These were reports from 1998, where Ethicon is finding degraded polypropylene. This is medical literature that comes out finally in 2012 that is catching up to what Ethicon knew back then.

I just said the word "chronic pain syndrome." You will not find that anywhere in the instructions for use.

Piet Hinoul is the medical director, medical

director -- or, in fact, was the chief medical director of Ethicon. And what does he say? He says, on January 7th, 2009, earlier in the morning: "I feel that patients after a TVT-O do have more pain than after Monarc." Just a little tidbit here that you should know about. Monarc is a competing device made by a different manufacturer. And that's what he's saying about his device, the TVT-O.

He writes, he's personally convinced that after having published some in the vicinity of the nerve branches of the obturator to the tape's trajectory, that the presence of this foreign body will induce more pain and will be responsible for some of the chronic pain syndromes. We submit that this evidence was never disclosed. This is two years, again, before my client's implant.

Less mesh equals less complications. You're going to see that, again, Piet Hinoul was acknowledging this in 2010 and knew about it years before that, that there were problems with the TVT-O.

I don't want to spend too much time on this, but I want to direct your attention, this is an internal company document, talking about leaving less mesh behind. That's an important concept because, as I told you, as Ethicon knew and the evidence will show, the less mesh equals less complications.

Look at the words "persistent pain," "chronic pain

syndromes." You will not find that anywhere in the instructions for use.

Talks about a key unmet need to the obturator. Don't forget that we're talking about the TVT-O which is in the obturator space.

Those are just some of the advantages of less mesh. We talked about it; I'll move on.

These are not routine postoperative complications, ladies and gentlemen. So when you hear that the TVT-O carries with it just risks like any other surgery, you're going to hear about some of the other alternatives that are available. There are competitors' devices, which we're not here about, so there are other mesh alternatives that are inserted differently, not the inside-out approach of the obturator membrane, and not with the same kind of mesh that's at issue in this case.

You will also learn that there's other non-mesh surgeries available. One is called the autologous fascial sling procedure. Another one is called the Burch procedure. And, of course, we have the TVT-O. Those are just some alternatives.

Does the autologous fascial sling cause chronic pain syndrome? No. Does the Burch? No. You'll learn the TVT-O does.

Pelvic floor muscle spasm. Autologous fascial sling

and Burch, no. TVT-O, yes. So when you're thinking about the benefits of the TVT-O, this is evidence that you can consider.

Sexual impairment due to scarring and contraction of the mesh. Remember that this mesh can shrink and can fold and curl up inside a woman's body where it's supposed to be forever. No with the autologous fascial sling. No with the Burch. The TVT-O, yes.

Difficulty removing? TVT-O.

You're going to learn, ladies and gentlemen, the evidence in this case, that medicine and science are finally catching up to what Ethicon has known about since at least 2004. Perhaps earlier. What am I talking about? This is in 2011, 2012 when my client was operated on by Dr. Siddique to try to take the mesh out, and what does he say in his deposition about operating in the obturator space and the difficulty with this surgery?

He says, "It's a matter of comfort level and there are places that are developing the comfort level to take those out. I don't know how many" cases -- "centers across the country. I know of one case report that I read" -- I'm not going to read the whole thing to you. You're going to see his video deposition played here.

But look at what he says at the end. You're going to learn, he's a very experienced urogynecologist. He says: "I honestly don't know where specifically to send people for

stuff like that." This is the experienced gynecologist that the implanting physician referred my client to in an attempt to solve her complications.

Ethicon, in 2004, is talking about the increased pain, the transobturator approach. Literature, you're going to hear a lot about the literature in this case. There's finally now being published literature that speaks about this very issue.

Difficulty removing the TVT-O device. Something Ethicon was discussing in the 2000s, all the way up through 2009. In 2012, there are now articles that are being published about the obturator foramen dissection and how difficult that is.

And remember the knowledge that Ethicon had for years before my client was implanted about putting this TVT-O device in lean and active women? We said this information was not disclosed. And we showed you the testimony from Dr. Byrkit that was on the monitor in front of you. It is only now, in 2014, that this is starting to come out.

Look at the conclusion of this medical literature: "These findings support previous evidence that leaner women experience greater pain following transobturator mid-urethral slings. Such findings may inform surgical planning and pre-operative counseling."

We submit that this is information that any woman

would want to know.

And you're going to hear a lot about studies.

Go back.

And you're going to hear information about randomized controlled trials and what they really mean. You should ask yourself, not only accept what you're told, but what -- what does this really show you? Think about the specifics. Remember when I talked to you about a study comparing one product to another? The issue here is safety. We're not comparing one product to another.

You may hear, for example, that mid-urethral slings have been called the gold standard. We're not here about mid-urethral -- all mid-urethral slings. We're here about the TVT-O laser-cut mesh device. And what's important about that is you will not see any evidence of any organization or society ever calling the TVT-O laser-cut mesh the gold standard.

Another thing about the gold standard is that it is the preference for what is being used most at that time, and it's typically supported by data. You will hear evidence that the Burch and autologous procedures and perhaps other procedures with mesh were alternatives.

What's important here? When you hear evidence about long-term data, remember what I said about the laser-cut mesh. I want you to pay attention to this author here, an

Ethicon-paid researcher. This is an Ethicon-paid researcher, Nilsson, seven-year paper, 11-year paper, 17-year paper. He's talking about the TVT and that data. Please don't forget that.

Here's what's also important about this evidence that you're going to see. What does this Ethicon-paid researcher say about laser-cut mesh? "Will not use laser-cut mesh. Does not have the same stretch profile of mechanical-cut mesh."

So when you are told about long-term data, remember that the laser-cut mesh came out in 2007. There is no 17-year paper or 11-year paper, and when you see Nilsson's name, remember what he said about laser-cut mesh. That is important, very important evidence for you to consider.

This brings us to one of the most important issues in this case and that's the need to disclose. We submit that there's no harm in disclosing, let me know; but there can be plenty of harm in not doing so. In this country, that process in the medical field is called "informed consent." It protects a patient's right to choose his or her medical care. A physician is required to get permission from a patient before that happens. That's a standard of care you're going to hear about in this case, and it's a standard that, frankly, is just based upon as much on good common sense as it is medicine. A doctor and the patient are entitled to know the good and the bad.

The evidence will show in this case that Ethicon is in the best position to know what's going on with its product. It actually has systems that are supposed to -- that are surveillance systems to see how its product is performing and, if necessary, to take action on its product or to update that instructions for use that we've talked about.

What are we now learning? The medical community is now reporting serious mesh complications. "Changed women: The long-term impact of vaginal mesh complications." Managing these complications is fraught with complexity.

We are now learning about the impact of mesh complications on emotional health. The number of women that are getting referred for complications has increased substantially. You're going to hear about this evidence. So when I talk to you about disclosure, keep what's now happening in mind.

And this brings us to the issue of warnings. That's the third safety principle. And what does David Robinson, that medical director, say? He says, "It's important for patient safety that all the significant risks and complications be provided to both doctors and to patients either from doctors or from information from the company."

There's the IFU. And I ask that you look at this language. This is what it says: "Transient leg pain lasting 24 to 48 hours may occur. It can be usually managed with mild

analgesics." Aspirin, Motrin, Tylenol. "Transitory local irritation at the wound site and transitory foreign body response." Chronic -- "This response could result in extrusion, erosion, fistula formation or inflammation."

The IFU, ladies and gentlemen, we would submit, is not supposed to downplay the risks. The words "minimal" and "transient" mean something. "Transient," I see here mentioned four times. That just means "transitory," meaning "short-term." It sends a message.

The -- remember that -- the slides that I showed you about degradation? The evidence will show that Ethicon felt it was important enough to put in the IFU that this mesh was not subject to degradation. So if you hear that there's no clinical implications to degradation, you not only can ask and sift the evidence as to what you see, but also what you don't see. You can ask yourself, why is that there?

That is Meng Chen, ladies and gentlemen. She's going to testify by video in this case. And she's the safety surveillance director. And what does she say about her experience? Going back to 2009, you're going to learn that there were thousands of complaints that were coming in to Ethicon. Meng Chen was actually fielding phone calls from patients, and what does she say? She says she had conversations with patients that they continued to experience serious life-changing-type pain, serious pain that affected

the quality of their life and their daily activities.

What else did she say? She was aware of patient reports where the patient told her that they would have painful intercourse for the rest of their life. She had those discussions.

What did she decide to do about it? Well, remember what I said about that word, "transitory," that it was short-term? What did she say to her superiors at Ethicon? This is evidence that you'll see in this case from Meng Chen. She is the Ethicon safety director. I mentioned a few minutes ago about the safety surveillance systems that are supposed to be set up to monitor what's going on in the field and, if appropriate, take action.

She takes action and what does she say? "Pardon me again, from what I see each day, these patient experiences are not transitory at all."

What does she also do? She recommends from the senior management perspective, again, the higher-ups at Ethicon, "One of the paths for a better preoperative consent," it's that informed consent that I talked about, "is to provide an updated IFU to the operating physicians reflecting the current knowledge of the manufacturers on the potential adverse reactions."

Update the IFU. Remember what I said very early on in this case, when I said that Ethicon knew that there were

serious life-altering events? That's evidence you're going to see, ladies and gentlemen, life-altering events. And I said that Ethicon made a deliberate choice not to disclose and not to update their IFU. You will learn that that IFU that has been in place since this product came out was never updated to reflect the knowledge. That's what the evidence will show, ladies and gentlemen.

The failure to disclose makes informed consent impossible. The frequency and severity of complications, chronic pain, difficulty of removal, degradation and hardening. In fact, they say degradation doesn't even occur.

Contraction and scarring, excessive scarring comes with mesh. You're going to learn that. We're not -- we're not talking about scarring in the traditional sense. You're going to learn a lot more about that kind of stuff. Informed consent is impossible. That's what the evidence will show.

And that affected Jo Huskey. Now, you've already heard and you've had an opportunity to briefly meet, not talk to Jo Huskey yet or hear from her. And I told you that some of this stuff is going to be personal. There's no dispute in this case that she had stress urinary incontinence. There's a record right there from her physician. And she discussed this procedure with her physician, this TVT-O procedure. And I submit to you that as we go through the evidence in this case and this case unfolds, that there's not a whole lot in

dispute.

Her current diagnosis, which should not be in dispute, but the evidence will show, it's pelvic floor myofascial pain and levator muscle spasm.

What's in dispute here is whether the TVT-O and the implant surgery and the explant surgeries that she's had were a cause of that levator spasm and whether Ethicon adequately warned Dr. Byrkit.

Let's talk just real briefly about Jo's activity level. Jo's activity level was high. You're going to hear that she was on the elliptical for sometimes eight miles at a time. She would walk, she'd walk with her dogs. Her husband and her enjoyed the outdoors, going on vacations. Her activity level has dropped dramatically since the TVT-O was implanted on February 23, 2011.

Let's talk about her visit with Dr. Byrkit real quick. Just so we're clear, she gave a full history to Dr. Byrkit. She told her about her prior hysterectomy. She even told her about a tonsillectomy. The evidence will show she told her about an appendectomy and a gallbladder surgery. She told her about prior back pain surgery, said she had indigestion and heartburn.

She gave a full history. This is key evidence. Why is it? When we talk about those contraindications, based on the information that Dr. Byrkit had, Jo Huskey was an

appropriate candidate for the TVT-O at that time. And so she was implanted with this mesh on February 23, 2011. It's undisputed that Mrs. Huskey suffered from an exposure through her vaginal wall from the mesh material, that it was literally coming through her vaginal wall. And it caused Jo and Allen Huskey pain with intercourse.

Mrs. Huskey and Dr. Byrkit made a decision to do something that's called oversewing in an attempt just to cover up the mesh to see if it would heal. Unfortunately, that operation did not work. The mesh is still visible in the vagina, and Dr. Byrkit recommends more treatment, someone with more expertise in treating these complications.

This is a little bit hard to see, but I want you to pay attention to something from this July 15, 2011, visit. I believe that's the last date that Jo saw Dr. Byrkit because Dr. Byrkit refers Jo to Dr. Siddique. What does he say? He says, "At this point her" -- I'm sorry. She says, "At this point Jo was very upset, which I can understand."

She goes to Dr. Siddique. She sees -- he sees that there's two centimeters of mesh, that at least he can see that much on examination. What's important? He sees her in August. He also sees her in October. He also sees her, I believe it's October 12th. And what's really important here when you hear the claims in this case, that he did a number of exams on her -- a number.

Let me read off what he found just real quick. He said her bladder wall is normal, no lesions, no polyps. Her mucosa was normal.

No viticulose [phonetic] was noted. I'll talk to you about that in a minute.

The notes regarding her vagina only mention the mesh. There's no mention of excessive scarring or anything like that.

So when you're deciding what caused Jo Huskey's levator spasm, remember Dr. Siddique's examination and some of the other evidence that you're going to hear in this case. Dr. Siddique eventually decides to do surgery. What does he find? He saw two centimeters of mesh when he examined her vaginally. Once he opened her up, he found there was a chronically infected space with woody, edematous tissue. That means swollen tissue. He uses Mayo scissors to literally try to cut this mesh out.

I talked to you about the remaining mesh. The remaining mesh went behind the pubic bone and it retracted and it was not digitally palpable. What that means is he could not find that mesh that retracted behind the pubic bone on examination. He talks here about how he tried to remove the mesh.

One thing I'd like you to focus on is how he tried to remove the mesh. He tied a silk suture to the mesh and

applied traction. He tried to pull this out of her vaginal tissues. He used the words "downright impossible to remove." What does he say? I used the word "levators" earlier. It's very important in this case when you're considering the evidence. What does Dr. Siddique find? He finds afterwards, pain lateral at levators behind the pubic rami. I want to go back to that operative note. "The mesh retracted behind the pubic rami." I'd ask that you pay particular attention to his description of the pain, where it was, and these records when this evidence comes in in this case.

What else did he say about this? This is not his record, this of course, is his deposition. He's asked:

"She's experiencing deep pelvic pain?

"Yes. She has pain at the levators behind the pubic rami bilaterally. So there's a muscle group that's lateral to the vagina, and when I pressed on that muscle group, she had pain.

"And what could that be caused by?

"That could be caused by the fact that she had surgery in that area, now for three times."

Ladies and gentlemen, that's the levator muscles. Again, I told you this is a very narrow dispute. There is a tender area that -- and "tender" is a gentle description, but there is a tender area right underneath the urethra where the TVT-O goes through. There's also spasm in the levator muscle,

as you can see right there, where the little red mark.

So when you -- let me take a step back. I want to mention one other thing about Dr. Siddique's treatment. Jo's pain gets worse after this surgery. And what does Dr. Siddique do? She gets three rounds, three separate times of what are called "levator injections." Levator injections, which are literally shots into her levator muscles in an attempt to stop the pain. Her husband is going to tell you what he saw in that regard.

So when you decide whether or not the TVT-O is the cause, you have to look at things like proximity and timing when it comes to the evidence. This includes evidence of the TVT-O implant and the explant surgeries, and you're going to hear that these explant surgeries don't just simply cleanly excise this little area around the TVT-O and neatly take this out. You've already seen testimony from Dr. Siddique about that. They literally have to try to cut this stuff out.

That's what the evidence will show.

And you can also take into account the evidence that will come in as to the timing of her levator and syndrome diagnosis. There is no evidence in the record that she had levator spasms or any kind of diagnosis like that prior to the TVT-O surgery. You can take that evidence into account.

You will hear evidence that the area of this spasm is directly in that area and, at most, is two centimeters away

from where this mesh was placed.

Here's one other really, really important fact because this picture does not do the insertion method justice. And I'm going to read this to you. You're going to hear evidence that the TVT-O course directly underneath the levator muscles on its way to the obturator foramen. That's that opening in the hip bone. The levator muscles, ladies and gentlemen, as you learn about the anatomy in this area, attach to the pubic rami.

So you remember those records, you remember those -- that testimony, and please take that into account as you hear the evidence come in in this case.

You will also hear that the levator wall spasm can be felt right through the wall of the vagina where the implant occurred.

Now, no one is suggesting that Jo Huskey did not have a prior medical history. She had a prior medical history and you're going to hear about that.

But, as I told you before, the evidence is going to show, this TVT-O device was designed for people just like Jo Huskey, who had children, who might have been premenopausal or postmenopausal. The device itself, you will learn and the evidence will show, was made for weakened tissues in the pelvis, designed by Ethicon that way. And you're going to learn that the medical issues that Jo Huskey had were either

well controlled or occurred -- some were more than a decade prior to her implant.

What am I talking about? You're going to hear that she had back surgery in 1997 and 2000. But before I get there, let me tell you what her own treating doctor told her before she got the TVT-O. This is a medical record in this case. Her doctor told her she had no chronic disorders. That's evidence that you can consider in this case.

Her 2000 back surgery, look at what the doctor says about her 2000 back surgery: "Overall, I think she's doing quite well. She's dramatically better. She's increased her activity appropriately. She's ahead of schedule."

She also had something called "sacroiliac joint pain," from time to time. She suffered from sacroiliac joint pain on and off for about ten years prior to the -- to the TVT-O implant. That's the anterior view and posterior view of the sacroiliac joint. The levator muscles, of course, are identified here.

She also had diverticulitis. Diverticulitis is generally asymptomatic. It can flare up. That's undisputed. And the diverticulitis that she had, she had a flare-up around the holidays in 2010, just a few months before she got the TVT-O. And diverticulitis, just so you understand, that's just pouches that form along the intestine and the colon, and this episode that she had, it started in the upper left

quadrant and it went down. And, yes, did it radiate down into her pelvis?

But here's what's important about that in 2010. She had an extensive workup two months before her TVT-O implant. What does her own implanting doctor say when she's dealing with the diverticulitis in the holiday season in 2010? "Unlikely gynecologic origin." It was eventually attributed to diverticulitis. Her implanting physician says that no less than three times in her records. "Potentially diverticulitis."

Let's talk about those medical issues. I said they were well controlled and far apart. Did she have issues? Prior medical history? We're not disputing that. This is the SI complaint, diverticulosis -- -litis complaint, and the levator spasm that we talked about. The levator spasm is diagnosed after her TVT-O surgery. So when you consider the evidence in this case, please do not forget proximity and timing.

Dr. Siddique says that she was limited by what happened to her. He believed that at the time it happened to her and he believed it at the time his deposition was taken. You're going to learn more about the warnings in this case that were given by Dr. Byrkit. You're going to learn why they were inadequate. I've shown you some of the reasons why they were inadequate.

She was not informed about the possibility of permanent pain. That's from her deposition. She does not know if she told Mrs. Huskey she could have completely new pain. The consent form, the informed consent that I talked to you about, was not specific to the TVT-O.

And you'll actually have this information in front of you have as you review the evidence in this case and have an opportunity to take it back to the jury room. I apologize, but that's a bad copy. There were no TVT-O specific warnings, and the warnings were just common to all surgery.

What did Dr. Siddique finally tell her when he -- after the surgery, after the injections, says to her, risk of permanent pain. That's what she's living with.

What Ethicon knew. Thousands of chronic back pain -- I'm sorry, back -- thousands of chronic pain complaints. What did they represent? Transient leg pain. Insertion and removal methods fraught with risk. And you're going to hear from medical witnesses that will talk about that, who actually trained with the inventor of the TVT-O.

What did they represent? That the procedure was shorter and easier. What Ethicon knew: Bad for active patients. What Ethicon represented: No patient restrictions.

Safer alternatives were available. So when you're considering whether this device was really necessary for Jo Huskey, consider whether that information should have been

provided in light of these alternatives.

Too much mesh. They represented TVT-O mesh is lightweight.

The mesh is made of polypropylene, subject to degradation. They said that the mesh is non-reactive and does not degrade.

Called it the gold standard.

I just want to take the opportunity, I know I took a lot of your time, and we will respect your time in this case and try to move it along as quickly as we can. But these are important issues and I hope that some of this has provided context for some of the evidence that we're going to go through in this case.

And I, on behalf of Jo and Allen and my entire team, I appreciate it. So thank you.

THE COURT: Ladies and gentlemen of the jury, it's 10:25, but it would be more sensible to take our break right now than to start the defendants' opening statement and then stop after only five minutes.

When you retire to the jury room, at all times during the case, do not discuss the case among yourselves or permit anyone to discuss it with you or in your presence, don't watch anything about it, listen to anything about it, see anything about it, don't use any social media, computers, cell phone, Twitter, tweet or make any electronic noise.

I hope you enjoy your doughnuts and coffee. I'll call you back in 15 minutes. Court stands in recess.

THE COURT OFFICER: All rise. Court is now in recess.

(The jury left the courtroom at 10:27 a.m.)

(A recess was taken at 10:27 a.m.)

(The jury entered the courtroom at 10:43 a.m.)

THE COURT: Ms. Jones.

MS. JONES: Thank you, Your Honor. May I proceed?

May it please the court, counsel, ladies and gentlemen of the jury.

Good morning. My name is Christy Jones, and along with David Thomas over there, I have the privilege of representing the doctors and scientists and men and women of Johnson & Johnson and Ethicon.

Ethicon is a company that's owned by Johnson & Johnson and, as you already know, Ethicon makes medical devices, and one of the medical devices that Ethicon makes is a device called TVT-O, which is actually called tension free vaginal tape, that's what the TVT stands for. And as you know now, Ms. Huskey's doctor, Dr. Byrkit, chose to implant the TVT-O in Mrs. Huskey in order to treat her stress urinary incontinence.

It cured her stress urinary incontinence. It worked. But Ms. Huskey, and we're here today because Ms. Huskey claims

that she had certain injuries as a result of the use of that. And there's three things that I want to talk to you about today and three things that are important.

First, the TVT-O was an appropriate treatment for Mrs. Huskey. She had stress urinary incontinence. It cured her stress urinary incontinence.

Two. Ethicon's responsibility is to warn doctors, that's important, doctors of the risks. And Ethicon did warn doctors of the risk associated with the TVT, and in fact Dr. Byrkit shared that information with Ms. Huskey.

And third, Ms. Huskey had health problems, including some of the very ones she claims today, long before she ever had the TVT.

Now, these are the three problems or the three points that I really wanted to talk with you about this morning. But frankly, after listening to Mr. Wallace, plaintiff's counsel, there's something I want to address with you first because I think I need to respond to it.

Mr. Wallace suggested that a manufacturer has a duty to put patient's safety first, and a manufacturer has a duty to insure that its products are safe, and that a manufacturer has a duty to warn of the risk associated with the product. And that's right. Of course that's true. And Ethicon did and fulfilled all of those responsibilities.

Ethicon, in fact, developed a revolutionary and

innovative product for the treatment of stress urinary incontinence in women, a condition that has plagued women for years. So revolutionary that it was immediately adopted by doctors all over the world as the preferred method of treatment of stress urinary incontinence in women. And Ethicon continued to seek to study and to seek ways to improve its devices over the years, exactly as you would hope a device manufacturer would do.

And that's why, ladies and gentlemen, point number one, the TVT-O was an appropriate treatment for Mrs. Huskey. If we start at the, again, let me start a little bit with the background on it, just bear with me. Stress urinary incontinence is a condition that has haunted women for years. It's a condition that will affect as many as one out of three women at some point in our lives. You have accidental unintentional loss of urine and it can be embarrassing, it can be disruptive, it can affect women and how they live their lives. And as a result of that, women have sought treatment for this condition, and doctors have explored different ways to treat this condition for decades.

It's so serious for women that women have been willing to under go major abdominal surgery looking for a cure. And that's the reason that the TVT was such an important development.

Let me see if I can put this into perspective and

explain a little bit, and I apologize that you're having to look at the pelvic anatomy one more time. This is just looking from the side view. You have the bladder, behind it the vagina, in the back the rectum, and then you have the urethra.

What's important is that before the TVT was developed, the way doctors treated surgically stress urinary incontinence was through major abdominal surgery where the vagina was essentially pulled up to support the bladder and the urethra to prevent the accidental loss of urine.

So if we look at this specifically, just to give you an example, and I'm not a doctor so bear with me in my descriptions here, what happened is is that the doctors would go in and they would have roughly a four-inch incision in the stomach to go in, and then they would turn around behind the retropubic bone to the vagina, and they would then suture or tack the vagina tissue up to the ligaments on the pubic bone. This is the pubic bone here. This just looks at it if you're looking down where they pull back the tissue, that's kind of the way it looks.

If you look at another view of it, what you have here is the bladder and the urethra, and you pull the vagina up to hold the urethra in place. You stopped it by holding the urethra in place, you supported those muscles and you would prevent the accidental loss of urine.

This procedure, and I roughly described it, sometimes called the Burch procedure, you'll hear about that. Plaintiff's counsel also mentioned what's called autologus fascial sling procedure, and that procedure is a very similar procedure where a sling is fastened or taken, made out of a person's own tissue, to hold up the urethra. So what they do is they cut a strip, either out of the leg or out of the abdominal muscle, and they make a sling, if you will, out of it. And then they do the same thing, they'll have this four-inch incision, they'll tunnel down it to reach the urethra, and in this case they also have to go up through the vagina, a separate area to place the sling under the urethra to kind of hold it, to hold it up.

Now, these are major surgeries that obviously involve putting someone generally under general anesthesia or under anesthesia and cutting them open. You have the risk of serious complications like infections or bleeding or all the complications that generally accompany any type of major surgery. Long recuperative period, about four to six weeks.

In contrast to that, in contrast to that, and the reason that what we're talking about today, the TVT-O, is that the TVT-O is an alternative to major abdominal surgery. Let's see if I can give you a little bit of background with it.

In the mid 1990s, the first midurethral sling, and the midurethral sling is placed under the middle of the

urethra there, was developed. It was developed in Sweden by a doctor known as Dr. Ulmsten. You'll probably hear about Dr. Ulmsten. Ethicon worked with Dr. Ulmsten to develop the original TVT, the original tension free vaginal tape. That device was very important. It was significantly different from the major abdominal surgery because they were able to take large needles and go up through the vagina and place a sling made of mesh up under the urethra to hold it up.

So when we look at this, this is the original TVT, and you just see what happens is they go up through the vagina and then they place this sling around the urethra just so it's supported. And then, rather than having a major abdominal incision, stomach incision of the four inches, you have these two little exit holes, almost puncture wounds, of which the tape comes out.

Now, this was a significant development because the procedure could be done in only about half an hour, it could be done with a woman in and out of the surgical suite, she didn't have to stay in the hospital all overnight in most cases, and in most cases she could resume her activities in a matter of days. So it was a significant advance.

It was first marketed in the United States in 1998 and immediately thereafter, immediately thereafter this became the doctor's preferred method of choice to treat stress urinary incontinence.

Shortly thereafter, Ethicon, I'm not even sure I said Ethicon, but Ethicon obviously is responsible for making the original transvaginal tape and put it on the market in 1998.

After it had been on the market and became so widely accepted, one of Ethicon's competitors began to develop and market a different type of transvaginal tape, one that went through the obturator foramen as you heard about this morning. These are just the little holes of the obturator and so forth. It was thought that this would be an advantage over the original TVT because the tape could come out, would run to the side, here, and out, rather than going up and risking the potential puncture and placement of it up the bladder. So it was thought that this was an improvement of the device.

About that same time as doctors got interested in it, Ethicon began to work with a doctor named Dr. de Leval who is at Liege University in Belgium. And Dr. de Leval was working on developing and had clinical studies in women and was developing what became the TVT obturator. The TVT obturator was implanted basically the same way that the TVT, the original TVT was, except for the way that the tape comes out and actually comes out now in the legs. Dr. de Leval had studies under way, Ethicon worked with him, and Ethicon then began marketing the TVT-O in 2004 here in the United States.

Now, you may ask yourself a little bit about why I'm talking about the TVT as opposed to the TVT-O which Ms. Huskey

had, and I want to answer that question because I think it's important that you understand that when you see both of them, you understand that the TVT-O was, in fact, the logical extension, if you will, off the TVT retropubic. The retropubic is called the retropubic, again, because the tape comes up behind the pubic bone and here it goes, it's called the obturator because of course it goes through the obturator.

But what's important is that exactly the same tape was used in both operations. The TVT and the TVT-O are made of exactly the same material, exactly the same size material, exactly the same amount of material is essentially left in the body after it's placed there.

Now, I want to talk with you a little bit about the mesh. The mesh that makes up the TVT-O, that's used there, is what's called Prolene polypropylene mesh. It's important because it's made of Prolene polypropylene. And I say Prolene polypropylene for one very important purpose. Mr. Wallace talked with you this morning about degradation of polypropylene. Well, Prolene polypropylene is a very specific kind and that will be important to us.

The Prolene polypropylene was first made by Ethicon in sutures back in the 1950s. Those sutures that were made to be used in any kind of surgery, whether it's heart surgery, knee surgery, whatever, it would last a lifetime. That Prolene polypropylene is exactly the same composition as what

is used in the TVT mesh.

In the 1970s those same sutures were woven into a mesh. It's just like you took the sutures and you wove them up and you have a mesh, exactly the same thing. And that mesh began to be used by doctors for treatment of primarily hernia surgeries. It was used in the abdomen to treat hernias and then doctors, some began to use them in other areas and in pelvic areas. That was in the Seventies.

So long before this tape was ever used in the TVT in 1998, it had been used, the same mesh, identical, had been used in thousands, if not hundreds of thousands, of men and women for treatment of different conditions in the body.

In 1998 it was first used in the TVT, after Dr. Ulmsten had done studies of it, beforehand, the use in women, and finally in 2003 it was incorporated into the TVT-O.

So what we see is that long before it was ever used in the TVT, it had been used, it had been studied in laboratory studies, it had been studied in clinical studies, and throughout that material had been shown to be safe and effective, no suggestion at that point there was any kind of degradation of the material at all.

One of the things that you will learn, that there will be no real dispute about, is that the TVT and the TVT-O are two of the most widely studied devices ever used in women. In fact, there are over 2,000 studies in the medical

literature that have looked at midurethral slings. And these studies look at the issue of whether they're safe and whether they work and they're effective, and these studies compare them to the other like major abdominal surgeries to see if they work effectively.

There are over a thousand studies or publications in the medical literature dealing with the TVT and TVT-O. Specifically, there are over a hundred randomized controlled trials dealing with the original TVT, and over 60 dealing with the TVT-O.

Now, I want to emphasize something because these were important. These randomized controlled studies are studies in which the device is implanted in women, and there's generally two populations of women, some have the device and some don't, and doctors follow those women and study them to see what happens to them. They look at it to see whether the device works, and they look at it to see whether there is some type of complication. We have more complications in one side than you do in the other. And so these types of studies are considered to be the very best type of study that can be done on medical devices.

We not only had all of these studies on the TVT and the TVT-O, we have other studies that were done before they ever went to market. For example, Dr. Ulmsten had studies beginning in 1996. Dr. de Leval had studies in, again, in

2003. And what we know is obviously there are hundreds of other studies that I haven't put up here that I've referenced earlier. And all of these, or at least the vast majority of these, were done and performed before Mrs. Huskey got her TVT-O in 2011. And consistently what these studies have shown, consistently, is that both the TVT and the TVT-O are safe and as effective as any of the major abdominal surgeries.

In fact, they've had studies that have gone and looked at them, in the case of the TVT, for as long as 17 years. In the case of the TVT-O, it hasn't been around quite as long, but there's studies going for as long as, you know, five years. And if we look at these types of studies, they looked at success rates. So these long term studies have looked to see is it successful, does it work. And they measure it two different ways. One is by objective standards. And by objective standards means what the doctor can measure. So can the doctor measure that, in fact, the woman is continent, does not leak, when she is asked to perform certain functions in the doctor's office.

And what these studies have shown, these are the long term studies on the TVT, have shown that after as long as 17 years, ten years, 11 years, you have objective cure rates, success rates, of anyplace between 84 and 91 percent. So eight out of ten women after ten years are still perfectly dry and it works.

The studies have also looked at it another way, and the other way they've looked at it is subjectively. And when we say subjectively, what that means is how does the woman feel about it. So the studies ask the woman, how do you feel about the success of this procedure, how do you feel about whether or not you think it works, and would you recommend it to a friend. And what in the case of the TVT studies they've shown is, again, you see very high subjective success rates, the lowest one here being about 78 percent, going as high as 95 percent. The women considered it to be a success years and years after they had the study.

We also have the long term studies on the TVT-O. Again, as I said, they're a little bit shorter than the long term because the TVT-O hasn't been around as long, but you see there that you also have very high success rates with the TVT-O, the lowest one here being a 73 percent success rate, meaning that three out of four people thought it was successful after five years. And on the long term studies, what the women thought about it, you also had an 80 to 90 percent success rate, with the exception of one which was a little bit of an outlier down to 62 percent.

But the important thing is that all of these studies demonstrate that both women were satisfied with the TVT-O and the TVT, and doctors thought that they had cured it.

Consistently all of these studies have shown that the

devices are safe and effective long term when compared with either the major abdominal surgeries or others.

That being the case, with all of these studies, doctors immediately, as I said, I think I'm repeating myself and I apologize, immediately began to use these devices to treat women for stress urinary incontinence. They used them because they found them to be safe and they used them because they found them to be effective. And when plaintiff's counsel suggested that they didn't look at safety, I suggest to you that every one of these studies, every one of them, looked at potential complications.

It's been so widely, so widely accepted that every major organization of doctors who treat this condition, every one of them, has endorsed the use of the midurethral sling. They said it's a big advantage over what we had before. You have efficacy, that means it works after five to ten years. You have low complication rates. And these slings, the midurethral slings, including the TVT-O, were now considered the worldwide gold standard for treatment of stress urinary incontinence by doctors.

And all of these statements, ladies and gentlemen, were issued after Ms. Byrkit had her surgery. They remain true today. Indeed, some of these studies, some of these statements, were made as late as 2014.

But notwithstanding the fact that doctors worldwide

use the TVT and TVT-O to treat stress urinary incontinence, every surgery has complications. And surgery involving the pelvic region, or to treat stress urinary incontinence, regardless of what it is, has the potential for complications.

The old surgical abdominal approach had these complications, and there's also a potential for the complication with the TVT and the TVT-O. They include such things as pain during intercourse, pain, bleeding, infection. They're all possible risks. But what's important about this, and the reason I'm showing this to you, is that doctors performing these surgeries and the major abdominal surgeries at the time all knew about these risks because they accompanied the abdominal surgeries long before we got to the TVT-O and the TVT. So everybody recognized that this was a possible risk. And what the studies show today is that these complications are very rare, generally in the context of the TVT or the TVT-O, but nonetheless they are potential complications.

Pain is a complication with every procedure. Clearly one of the things that is warned on and we'll see is the potential risk of pain. And to be candid, there are studies and you will probably hear that there are some suggestion of an increased risk of pain, particularly leg pain or thigh pain with the TVT-O because that's where the tape exits, if you will, over other things. But, generally, that pain resolves

in a matter of hours or days, and certainly within a few weeks.

What's important for us today in this case is that Ms. Huskey doesn't have that, never complained about it.

There are also some very specific risks that are associated with any foreign body that you put in a body. Anytime, whether it's a knee replacement or a heart replacement or whatever, there's always the possibility of something happening as a result of having that foreign body implanted. What happens is when that device is implanted, the body, just as part of its normal healing process, has what's called kind of a foreign body response. And what that is a inflammatory type response. In the case of the TVT-O, that inflammatory response is something that's anticipated because what happens is the inflammatory response helps the tissue actually grow into the holes in the mesh, the pores of the mesh, and that helps hold the tape where it's supposed to be. It's a little bit like, not very scientific, but it's a little bit like Velcro, it holds it there. And there's always the possibility that you can, that that can potentiate an infection or the inflammation can cause that, but that is extraordinarily rare, very rarely happens.

What does sometimes happen is that you have what's called mesh exposure, which is what we're dealing here with Ms. Huskey, where the tissue around the mesh will -- where the

mesh will become exposed in the tissue. So, for example, if it's exposed in the tissue of the vagina, it may pose some problems during intercourse or may be somewhat tender. Usually that exposure can be treated either -- sometimes it doesn't occur, doesn't have any pain or anything else associated with it -- a lot of times it can be treated just with an estrogen cream, and sometimes by surgeons just going in and clipping it away. But clearly mesh exposure is a risk that was known and explained as it related to the TVT-O. That occurs in, depending on the study, somewhere in the neighborhood of two to three percent of patients.

Regardless, regardless, what is clear is that even with the complications, what the studies have shown is that when you had a TVT-O as opposed to a major abdominal surgery, it's done with less anesthesia, shorter operating time, shorter hospitalization time, you're able to resume activities quicker, with generally a low rate of complications, but lasts just as long. For those reasons, for those reasons, the TVT-O was an appropriate treatment for Mrs. Huskey.

So I want to turn now to point number two that I mentioned, and that is that Ethicon's responsibility is to warn the doctors of the risks. As I mentioned, every surgery has complications, and those complications are what surgeons or doctors need to know about, and that's what the manufacturer's duty is to do is to warn the doctors.

Ethicon tried three different ways or several different ways to make sure that doctors were aware of the risks. First, it provided professional education to doctors. In providing professional education to the doctors, what I mean is they would give seminars where they would come and listen to a lecture, but they would also provide them the opportunity to be trained on how to insert the TVT-O on cadavers, or to observe surgery by more experienced surgeons, or to have a more experienced surgeon watch them so they could insure that they knew how to insert the TVT-O correctly.

We also provide instructions for use with every TVT-O, and those instructions for use include the risks -- not only how to do it, how to do the procedure, but include the risks associated with it. And then the third, the patient brochure was provided to doctors to help them counsel their patients on risks.

If we look specifically at the risks that are included in the IFU, what's important is this is information that's given to doctors. You may puncture vessels or nerves. You may end up having to have a repeat surgery if there's a problem here. You may have, the erosion or extrusion relates to the mesh exposure. You can have inflammation. You may have an infection. And all of this information was given to doctors. And Dr. Byrkit, Mrs. Huskey's surgeon, has testified -- and you will see her deposition exactly as it is -- that

she was aware of these risks, that she had used the TVT-O repeatedly, and indeed that she counseled Ms. Huskey on the risk.

In fact, she was asked, "Would the possibility or the risk of pain after the procedure be present in all of the surgeries?" "I would expect that there could be pain in any of the procedures, yes."

She's asked specifically about what she discussed with Mrs. Huskey and what she knew, and she said that she specifically discussed with her that mesh can erode and there could be complications, potentially complications after mesh erosion that need to be treated.

Then we asked about pain with intercourse, and she talked about the fact that although she couldn't say specifically that she used the words "pain with sex" or "pain with intercourse" in talking with Ms. Huskey, that she certainly knew it and thought that it was obvious because you were operating in the vagina and the pelvic area.

The records in this case show that Ms. Byrkit -- Dr. Byrkit counseled Ms. Huskey three different times about the risks associated with the TVT-O, and specifically talks about the risk of infection, the risk of damage to internal organs, the risk of mesh erosion, the risk of the need for further surgery to remove the TVT. So clearly Dr. Byrkit recognized the risks that were associated there and, according

to the records, discussed them with Ms. Huskey.

Now, although Ms. Huskey has testified that she doesn't remember exactly these discussions, the medical records also indicate that she was given a pamphlet on TVT, the patient brochure, the first time she consulted Dr. Byrkit about that. Again, we don't, Ms. Huskey doesn't have that pamphlet any more, we don't have the one specifically that was there, but the one that was in effect beginning as early as 2008, almost three years before Ms. Huskey's surgery, specifically warned of pain, pain with intercourse, the mesh material becoming exposed, and exposure may require treatment.

This is important, ladies and gentlemen, because what the evidence will show is very specifically that Ethicon warned the doctor of the risks associated with the TVT-O, and in this case Dr. Byrkit's testimony is that she shared those risks with Ms. Huskey.

Third. We talked about Ms. Huskey had health problems before she had the TVT-O. If we look and begin with Ms. Huskey's medical records in 2010, in early 2010, here in March, she went to see the doctor with increased urinary symptoms indicating that she was having some stress incontinence. This is the first time, I think, that she complained of stress urinary incontinence in the medical records, certainly in 2010. And noted at that time that she works in physical therapy, actually teaches women's pelvic

strengthening. I mention that only because while we're talking about the surgical options here for treatment of stress urinary incontinence, there are sometimes doctors initially try and get women to do exercises to try and strengthen their pelvic muscles to see if they can avoid surgery that way, and that's what Ms. Huskey as I understand was looking at. And she thought that this was, it was, the doctor thought that, it was alarming to her.

In 2010, a year before Ms. Huskey got the TVT-O, was a little bit of a difficult year for her. You can see she had the urinary problems. She lost her job. She was treated for stress and depression. And then in the fall of 2010 she began to complain and see doctors for abdominal pain, suprapubic pain, pelvic and left lower quadrant pain, back pain, vaginitis and so forth. And this all starts in about October of 2010. It culminated when she was hospitalized following a trip to the emergency room in December of 2010.

And when she went to the emergency room in December of 2010, she was complaining about chronic left lower quadrant pain that had existed for the last month and a half, that had been rated seven to ten for four days, was radiating into her back, and it became significantly worse that day. She goes to the emergency room and she undergoes a series of tests over the next two or three days. She's actually hospitalized and doctors do a number of tests to look at that, including

looking and exploring abdominal or gastrointestinal explanations. And she was ultimately diagnosed with diverticulosis where you have some pockets in the rectum. They also looked at whether or not this was being caused by musculoskeletal problems, spasms or whatever in terms of her pelvic pain.

Let me just say that the records will show, you will see, that no definitive cause for her pain was ever identified at this point in time. It was at this point in time and during this hospitalization that she actually saw Dr. Byrkit for the first time. And it was after that when she first saw her in the office on January 27, 2011.

When she sees her January 11 -- January 27, 2011, she goes in to, kind of in part as a follow-up to her hospitalization, and it says she has multiple complaints today including left lower quadrant pressure mainly after intercourse, a constant vaginal irritation. And then we talk about she's leaking with urine and she describes the symptoms of the stress urinary incontinence.

This is why she went to see Dr. Byrkit. It was at this visit when she was talking to Dr. Byrkit that they discussed the potential treatment of her stress urinary incontinence and the potential treatment with the TVT. And it's referenced there, she gave her a pamphlet and they discussed it. And as I mentioned, she, according to the

records, talked with Ms. Huskey about it on three different occasions.

Following that, on February 23, Ms. Huskey actually had the surgery with the TVT-O implanted. Now, during the course of the surgery Dr. Byrkit had a little bit of a difficult time because she was inserting the TVT-O up through the vagina and she actually did what's called buttonholing, which meant that the mesh was actually kind of coming through the vagina, the vaginal tissue rather than being behind it. It's just a surgical risk that doctors know about when they're doing that, and what she did was she removed the tape, sewed up the little holes, repassed the tape, and placed the rest of the TVT-O then without any further complications.

Ms. Huskey went home, cured, no problems with stress urinary incontinence, had no problems for a week or so. And then, about March 5 or so, she was vacuuming and I think playing with the dog or something, I think, and noted she had some vaginal bleeding. She called the doctor. Ultimately it wasn't bad enough for her to go back in, but she did go back in to see Dr. Byrkit on March 9. This is her first post op visit, a little over two weeks afterward.

At the time that she went in to see Dr. Byrkit then, she was dry, having no problems with stress urinary incontinence. She was having -- she reported that she was pleased with her surgery. She was having no problems, no

further problems with bleeding. And on the examination Dr. Byrkit found that she was not tender, had no complaints of pain at all.

Now, she did note, Dr. Byrkit did note at that time that there was a small exposure of the mesh in the vagina. She discussed it with Ms. Huskey, suggested that she use the Premarin cream, which is the estrogen cream, just to see if that would take care of it, but it was causing Ms. Huskey no problems, she had no pain or tenderness around it. There was no indication that she had any type of infection.

And on March the 16th, a week later, Ms. Huskey actually goes back to work at a new job as an assistant physical therapist where she's providing therapy and working with patients in a pool and so forth, so she's gone back to work by March the 16th without having any problems whatsoever.

She comes back in on April the 6th for another post op visit, and again, at this time she's not having any problem. She's not leaking, she's gone back to work, she's not tender, she's not having any signs of infection, but Dr. Byrkit again notes that the mesh is still exposed. She talks with Ms. Huskey about it, according to her records and her testimony, and they talk about various treatment options about whether you could do nothing, use the cream, whether they ought to go back in and try and cover over it, and they decide to do nothing, but in fact she suggests to her to wait until

after she has intercourse so she can see whether it's causing any problems.

And in fact, then she comes back for her annual exam on May 20, and when she comes back for her annual exam on May 20, Ms. Huskey reports that she's walking, biking, in the pool one to two hours a day, five days a week. Again, she's not leaking, but she does report that she has had some discomfort with intercourse. And Dr. Byrkit notes that she still has a small mesh exposure. Again, no indication of tenderness with the mesh exposure and no discharge or indication of anything like infection.

Nonetheless, they decide to have another surgery in order to cover up the mesh, if you will, sew over the mesh, and so Dr. Byrkit goes back in and takes the plaintiff back to surgery to do that on June 29.

Two weeks later, July 15, Ms. Huskey goes back in to see Dr. Byrkit. At that point, even though the surgery went well and without complications, at that point she complains of lower abdominal pain for two days. That's the first complaint of pain following the TVT-O surgery in Mrs. Huskey's records.

As counsel noted earlier, she was still seeing a small one centimeter exposure and reported that to Ms. Huskey. Ms. Huskey was upset and she referred her, Dr. Byrkit then referred her to Dr. Siddique, who she saw on August 29 the first time. And when she sees Dr. Siddique on August 29,

she's complaining of pelvic pain, rectal and pelvic pain due to diverticulosis.

Dr. Siddique examines her, notes that she still has some exposed mesh, and they make plans for a surgery to remove or to excise the mesh, but it's delayed until about November. He scheduled it about three months away as opposed to immediately.

And in the interim he actually does an cystoscopy on October 12, and what's important about that is that that was a procedure that they went in to see whether or not she was having any mesh anywhere else, whether there had been any erosion into the urethra or into the bladder or anything, and they didn't find anything, no problems.

So on November 18 Dr. Siddique excises the mesh, the tape up underneath the urethra, without any problems according to his records.

Now, this is important. Dr. Siddique removed the mesh. When he removed the mesh, he sent it to pathology or whatever the normal places are, but he noted nothing unusual about the mesh. Dr. Siddique didn't note any degradation of the mesh. He didn't note anything unusual about the appearance of mesh. And we don't have the mesh, it just doesn't exist any more, and so you will not have any evidence before you, nor will anyone be able to talk to you based upon an examination of the mesh that suggests that Ms. Huskey's

mesh degraded or didn't perform in any way, shape or form in her body.

After this, Dr. Siddique followed Ms. Huskey for several months and, Ms. Huskey, in all candor, saw some other doctors, and went to see some other doctors complaining of pelvic pain and dyspareunia. And dyspareunia is just pain with sex.

And those doctors consistently looked to see whether or not there was any explanation for the cause of her complaints of pain. And you're going to hear from some of those doctors.

One of those doctors is Dr. Mueller. Dr. Mueller is a urogynecologist, and a urogynecologist is a specialized doctor who treats women with stress urinary incontinence and other conditions and is the one that actually performs this type of surgery. But she went to see, was referred to see Dr. Mueller for pain, and Dr. Mueller examined her. And Dr. Mueller ordered what's called a pelvic ultrasound to look at, and she ordered the ultrasound so she could look at it and see whether there was anything in Mrs. Huskey's pelvis that would suggest any reason for the pain.

The reason she did the ultrasound, Were you able to determine through your examination or through the ultrasound what that area was, had been referred to. And she said no, but I was able to determine it wasn't mesh.

And then she was asked whether or not there were any other abnormalities shown on the ultrasound, and she said no. It was perfectly normal.

Ms. Huskey also consulted Dr. Ogunleye. Dr. Ogunleye is another urogynecologist and he also examined her. And this is what he said: Where she had the pain is not where a TVT-O would be. I didn't see anything on her, and she is having the pain more on the posterior side of the vagina, that means frankly away from where you would have expected the TVT-O to have been, and not where someone who had a TVT-O would have mesh placed to cause the pain.

That's what Mrs. Huskey's doctors have said.

So I suggest to you, ladies and gentlemen, that in the course of this case it's going to be important to listen to the evidence to determine when Ms. Huskey began to experience the very claims -- the very pain and injuries that she claims to have sustained, and two, whether or not they have anything to do with the TVT-O.

Now, when we were here last week Dr. Goodwin -- Judge Goodwin instructed you and told you that the plaintiff, told you a little bit about the plaintiff's case and what the claims were and that the plaintiff had the burden of proof in this case. The plaintiff has essentially two main claims that Judge Goodwin talked with you about, one of which is a failure to warn claim, that the plaintiff has to prove that she failed

to adequately -- the plaintiff has to prove that Ethicon failed to adequately warn Dr. Byrkit of the risks associated with the TVT, and, two, that that failure to warn caused the injuries to Ms. Byrkit, I mean Ms. Huskey.

What you will also learn is that it's not necessary to warn a doctor of things that they already know, or which they say they already know and recognize. But we have already talked about that and I don't want to go back over and talk about the fact of the warnings. What I do want to talk to you is the plaintiff's second claim of defective design.

Do you remember what Dr. -- what Judge Goodwin said was that the plaintiff has a defective design claim, and in order to prove that she must prove that the TVT-O, that there was a condition in the TVT-O that made it unreasonably dangerous, and that that condition proximately caused her injuries.

Now, when we're talking about, when I was listening to counsel this morning, how plaintiff intends to prove defective design, it appears that there are three particular issues. One is that they claim that the mesh that Ms. Huskey had was a laser-cut mesh; and it was. Two, that the mesh somehow degraded. And three, that maybe there was too much mesh or the wrong size or type of mesh that was there. So let me quickly address those.

First of all, when we're talking about laser-cut

mesh, obviously this is blown-up and very difficult, but what we're talking about here, we're talking about laser-cut mesh, the mechanically-cut mesh that was in the original TVT and TVT-O is just like if you took a paper cutter or pair of scissors at the school and slashed it. That's what a mechanically-cut mesh is. The laser-cut mesh is just if you cut it with a laser, so it kind of melts the edges of it, if you will. Other than that, other than the way they are cut, these two pieces of mesh are identical. Identical. And the only thing that may be a little bit different is that here on the edges it may be a little bit stiffer.

Now, the reason that that laser-cut, that the change to the laser-cut was made, was because some doctors complained about the appearance of the mechanically cut mesh and they thought that there was some fraying on this edge. So the move to the laser-cut mesh was seen an improvement to the product to address some of the concerns that had been expressed by doctors.

What's important about the laser-cut mesh is this: One, it's identical in every other respect to mechanical-cut mesh that's been out there for years; two, Ethicon tested and evaluated the laser-cut mesh to determine whether or not there would be any change in the physical properties of the mesh that you would be expected to have any clinical effects; and three, that there would be no evidence whatsoever that the

laser-cut mesh had any medical effect on Mrs. Huskey.

The second point plaintiff raises, the claim that the polypropylene mesh somehow degrades. The reason I started with the sutures, talking about the sutures, ladies and gentlemen, is because the sutures are made of exactly the same material. They've been used in the body for over 50 years now. They're placed in the body with the expectation that they're going to last a lifetime. And in fact, that's what happens.

The mesh is made of Prolene polypropylene, that's a special formulation with some antioxidant characteristics to preclude it from degrading in certain circumstances. As I said before, there will be no suggestion or indication that the mesh itself that was removed from Ms. Huskey was in some way degraded. There will be no evidence that degradation had any clinical or medical effect on Ms. Huskey.

Third point that is sometimes raised or suggested is that there's too much mesh, that this is a heavier weight mesh, that the hernia mesh is a heavier weight mesh than used in other applications. They claim that the pore size is too small and there's a reference to it as large bore, small bore. I want to just say these things about it: One, a large bore mesh is defined as a mesh that has pores, little holes, larger than 75 microns. The pore size of the TVT is over a thousand microns. Granted, it's obviously blown up, that one inch

here. This would be considered a large bore mesh, this is a larger bore mesh. This is the pore size of the TVT-O.

Now, the only reason that I raise that with you is that in some of the documents that you will see, and maybe even some of the testimony that you will hear, there's going to be reference to -- in fact, on the plaintiff's slide they suggested that there's old construction hernia mesh. There's a suggestion that the old construction hernia mesh and the mesh that was used in the TVT-O is somehow a small bore mesh that has problems with it. And I have to tell you, frankly, ladies and gentlemen, that there's some sloppy language in the documents where they refer to it as small bore mesh, probably because subsequently a larger bore mesh used in other applications for pelvic or repair surgery and hernia surgery was developed. The right way to do it would have been to call it large bore and extra large, or large and larger. But as you can see how it happens, somebody referred to it as small. It may be confusing to you when you look at some of the documents. I'm going to ask you when we talk and look through the documents and you hear the testimony of some of the witnesses, it will be important to discern or listen to which mesh they're actually talking about.

What is important is that it is a large bore mesh. It was a large bore mesh when initially tested by Dr. Ulmsten in the mid 1990s, it's still a large bore mesh, and study

after study after study has shown it to be safe and effective.

Now, it's time for me to slow down. This will be the last time I have an opportunity to address you until at the end of the case. As Judge Goodwin has told you, the plaintiff gets to present her evidence first, and I do ask you, as Judge Goodwin cautioned you, to keep an open mind until you hear from our witnesses, which will probably be several days from now.

At the end of this case I think what you will find, based upon all of the evidence, is that, in fact, the TVT-O was an appropriate device to treat Ms. Huskey's stress urinary incontinence, that Ethicon warned of all of the conditions that Ms. Huskey claims to have experienced, and these were all done by Dr. Byrkit, and that the product was not defective.

Stress urinary incontinence, ladies and gentlemen, is a condition for which women need treatment and have been seeking treatment for decades and decades. The proof will show that the TVT and the TVT-O were remarkable devices needed by women and doctors, and that they're safe and effective.

And so at the end of the case, I'll come back to you and I'll ask you to return a verdict in favor of Johnson & Johnson and Ethicon.

Thank you.

Thank you, Your Honor.

THE COURT: Ladies and gentlemen of the jury, I

rarely vary from the schedule, but we would barely get the witness sworn and it would be noon, so we'll be back at five minutes till one. We'll take a break for lunch.

During the lunch hour do not discuss the case among yourselves, permit anyone to discuss it with you, or in your presence. Don't read anything about it, watch anything about it, listen to anything about it, use any social device, social media, computer. I think you'll get the drift after I say this about 50 times. Actually I know you got it the first time, but I've got to be sure somebody doesn't think I got it wrong.

Have a good lunch. We'll see you back.

(The Jury left the courtroom at 11:55 a.m.)

THE COURT: Court's in recess.

(A recess was taken at 11:56 a.m.)

(The jury entered the courtroom at 12:55 p.m.)

COURT SERVICES OFFICER: All rise.

THE COURT: Good afternoon. I trust you had a pleasant lunch. We're ready to begin the presentation of the evidence.

The plaintiff, if you will call your first witness. Mr. Wallace?

MR. WALLACE: Yes, Your Honor. Dr. -- the plaintiffs would call Dr. Scott Guelcher to the stand, please.

THE DEPUTY CLERK: Sir, if you'll please raise your

right hand.

(**SCOTT GUELCHER, Ph.D.**, HAVING BEEN DULY SWORN, TESTIFIED AS FOLLOWS:)

THE WITNESS: I do.

THE DEPUTY CLERK: Thank you. Please take the witness stand.

THE COURT: You may proceed.

MR. WALLACE: Thank you, Your Honor.

(DIRECT EXAMINATION OF SCOTT GUELCHER, PH.D., BY MR. WALLACE:)

Q. Could you please introduce yourself to the jury.

A. My name is Scott Guelcher. I'm currently an associate professor of chemical engineering at Vanderbilt University in Nashville.

Q. How many years of experience have you had in chemical engineering?

A. Over 20 years. Yeah.

Q. And have you ever worked with medical device companies before?

A. Yes, sir. My current research, I'm a professor of chemical engineering, but my research is in the area of biomedical materials and a number of these materials, we're working with companies to determine the products for human health such as bone void fillers, other types of bone grafts and products for healing foot ulcers and these types of products.

Q. Dr. Guelcher, rather than marching through your C.V., what I'd like to do is I have prepared a PowerPoint that outlines some of your qualifications and some of the topics you'll talk about today. If we could show that on the screen, please. Counsel?

MR. THOMAS: Do you mind if have a copy?

MR. WALLACE: We are getting a printer.

THE COURT: Do you have -- do you have any problem with just going ahead?

MR. THOMAS: No, Your Honor.

THE COURT: I figured you looked at it before.

MR. THOMAS: I haven't seen the PowerPoints, but that's fine. We'll go ahead.

THE COURT: All right. Go ahead.

MR. WALLACE: Thank you, Your Honor.

BY MR. WALLACE:

Q. You've already talked about working at Vanderbilt University. Can you tell me about the textbook on biomaterials that's listed there on that slide?

A. So, a number of years ago, I co-edited a textbook on biomaterials, and this covered a number of different types of biomaterials that are used for implants and we talked about properties of the materials that are used in the clinic, and this was intended primarily as a teaching textbook for undergraduate and graduate students.

Q. Okay. When you talk about biomaterials, what are you referring to?
A. So, these are materials that their purpose is to be implanted in the human body and to serve some goal, either healing bones, say, or hernia mesh or these different types of materials that have been designed to achieve a medical goal.
Q. It says that you've given over 200 scientific presentations. We obviously don't want to hear about all of them. But can you tell us what you mean when you refer to scientific presentations?
A. So, these are presentations given in meetings or scientists working in a certain area. For example, there is a Society for Biomaterials, and we all meet once a year and present our latest research, my students and I present at these meetings, and there is a number of them that are listed there that I attend regularly.

MR. WALLACE: Can we go to the next slide, please.

THE COURT: Do we have copies for defendants now?

MR. WALLACE: Yeah.

The one -- just a housekeeping issue.

Dr. Guelcher --

THE COURT: We have the jury monitors on. That's one of the reasons I wanted to have the defendants look at it, to be sure there's no objection before we go further.

MR. WALLACE: Sure, thank you, Your Honor.

THE COURT: So let's just hold for a second.

MR. WALLACE: Sure.

MR. THOMAS: Do you want me to review what's on the monitor, Your Honor?

THE COURT: No, I asked them to go get the rest of them. I didn't realize there was going to be more than one.

MR. THOMAS: Thank you.

MR. WALLACE: We had a -- Your Honor, we just had a slight IT problem over lunch.

THE COURT: Okay.

MR. WALLACE: There's, apparently, the first-day jitters somehow infected the IT.

THE COURT: There is a what?

MR. WALLACE: We had some first-day jitters, I think, in the room outside where we're printing some things, and we weren't able to print. So I apologize, Your Honor.

THE COURT: Well, you're apologizing to the right guy because I never have a problem with IT.

(Laughter.)

MR. WALLACE: I don't, either, Your Honor.

THE COURT: If you can't print it, we'll -- could you take it over and show it to them?

MR. WALLACE: Sure. And I will represent to -- I believe counsel has seen something like this previously, but I'll represent to you that the first three pages and perhaps

the first 15 or so minutes is strictly going through the doctor's background, if that's okay with you.

MR. THOMAS: That's fine.

THE COURT: All right. Let's go ahead and proceed with it.

MR. WALLACE: Thank you.

BY MR. WALLACE:

Q. So let's go back to that screen, Dr. Guelcher. I see a lot of what I call acronyms, DOD, AFIRM, et cetera. Can you just quickly walk through each of those and tell the jury what they mean and a little bit about the grant process?

A. So, as a professor in the engineering school at Vanderbilt, one of my responsibilities is to write grant applications to federal agencies, to receive money to support the research that I use to pay students that I pay for materials. And these are a number of funding agencies. So the first, the NIH, is the National Institutes of Health.

There is an institute that focuses on arthritis and bone diseases. I have funding from them.

The NCI is the National Cancer Institute, and in these types of programs, we're interested in the problem of how does breast cancer damage bone, how does it metastasize in bone, why does that happen, how do we treat it?

The last one is probably familiar to everyone. DOD is the Department of Defense, and the Department of Defense

has a very large program called Armed Forces Institute of Regenerative Medicine, that's AFIRM, and that's a program that involves about 20 universities and we're all working together to find better treatments for soldiers that are injured in the conflicts in Iraq and Afghanistan.

So, my primary contribution there is on bone grafts to repair the mandible, so there's some very bad craniofacial injuries. Survival rates are high in these wars, but soldiers have devastating injuries that affect their quality of life. So we're working to improve that through that program.

And the last one is the National Science Foundation, which is -- has a very important education mission as well, training grad students, so those are currently agencies that I've applied for funding and have grants through them right now.

Q. Do you have a particular area of research as it relates to wound healing, Dr. Guelcher?

A. So, we are designing tissue grafts for healing skin, so that would include things like diabetic foot ulcers. It would also include problems with the wound vac, so you have a very bad wound, they can put a vacuum on it to kind of clear it out and help it heal better. We're working with a company to design better foams for this procedure. So we work with a number of wound-healing companies.

Q. Beyond the experience that you've described, you actually

worked at chemical companies before. Is that right?
A. That's right.
Q. Can you tell us a little bit about that?
A. So, right after college, I worked for Eastman Chemical Company in Upper East Tennessee. There I was working on polyesters, nutritional supplements such as vitamin E, vitamin A.

After my Ph.D., I worked here in South Charleston, at the Tech Center for about three years, so I was there when Bayer had a facility at the Tech Center, as well as Dowe. I worked a lot with the South Charleston plant, just trouble-shooting problems there, improving their processes, and this was all polyurethane intermedia when I was at Bayer.
Q. Okay. Can you do me a favor? I just want to break that up into two parts because you mentioned polyurethane. You mentioned plant. You mentioned South Charleston. Could you just take those one at a time for us?
A. Okay. So I started off at Bayer as a research engineer, working in the polyurethanes division, and my responsibilities there included designing new products that we would then translate to the plant. So we would make some improvement in the lab, and then we'd work with the plant to make sure that they could do this in a cost-effective way. I did that for about three years, until I left in 2003.
Q. From Charleston?

A. From South Charleston, yeah.
Q. And when you left South Charleston, West Virginia, where did you go?
A. Then I went back to Pittsburgh for a post-doctoral fellowship in biomedical engineering. That's when I shifted fields somewhat.
Q. In addition to working for chemical companies as an employee in your research, have you ever consulted with medical device companies or other chemical companies?
A. Yes. So, I've done a fair amount of consulting work with biomedical device companies, we're working with a -- a major goal in my research is what we would call "translational." So, that is, we try to discover things in the laboratory that are new and then translate that to help people by making better products. That's a very difficult thing to do because universities do research and companies make products.

So, a lot of these I've been working on for some time, but we work with the company to translate what we do in our laboratory to make a product better, and then the company will license this and then turn this into a commercial product. So I have several projects like that going on right now. So, a very keen interest of mine is innovation in the biomedical device industry, is a very important thing to me. So...
Q. Have you worked in the field of polymers, Dr. Guelcher?
A. So, I've been working in polymers since I graduated from

college, even while I was in college, so working with different types of materials, polyesters, polyurethanes, a number of different polymers over 20-plus years.

Q. What is a polymer?

A. So, a polymer is -- you might think of it in terms of a plastic, so you think about the seats that you're sitting on right now, they have a polyurethane foam inside. That's what makes it more comfortable than a slab of wood. Your mattress has a polyurethane foam. So, essentially, it's a plastic material that, many cases, is typically derived from oil chemicals, petrochemicals, that -- and you start with a very small molecule and you grow it into a long one, and then the properties of these polymers are very important, yeah.

Q. Does the work that you've done in this case concern polymers?

A. Yes. Specifically, an active area of my research is how the body responds to polymers. If you place a polymer in the body, what does it do? Do you want it to go away, do you want it to be stable? So a lot of my work focuses on how cells and tissues in the body respond to polymers. And I certainly think that this case falls within the scope of that question.

MR. WALLACE: Your Honor, at this time, plaintiffs would offer Dr. Guelcher as an expert in the field of chemical engineering and biomaterials.

THE COURT: Any voir dire?

MR. THOMAS: No, Your Honor.

THE COURT: He may offer his opinions.

MR. WALLACE: Thank you, Your Honor.

BY MR. WALLACE:

Q. Before we get to those opinions, Dr. Guelcher, have you been paid for the time that you've spent working on this case?

A. Yes, I have been.

Q. And how long have you been working on the issues of polypropylene mesh?

A. I'd say at this point probably in the range of hundreds of hours. I spent a lot of time reading many scientific papers and documents.

Q. Can you tell us just approximately how many scientific publications you've reviewed in the work that you've done in polypropylene, if you know?

A. Probably exceeding 50, 60 papers, maybe more. There's a lot.

MR. THOMAS: Your Honor, may we approach?

THE COURT: You may.

MR. THOMAS: Thank you.

THE COURT: Ladies and gentlemen, I forgot to tell you, there will be occasions when we go to sidebar, just like we did earlier today. When we do, you're not supposed to hear what we're talking about so I turn on the sound machine, but I ask you to talk among yourselves and be your own sound

machine.

(The following occurred at sidebar.)

THE COURT: All right. Mr. Thomas.

MR. THOMAS: Thank you, Your Honor. Counsel, as the Court is aware, has tendered us a PowerPoint presentation of Dr. Guelcher's testimony.

THE COURT: Um-hum.

MR. THOMAS: Paragraph E is an opinion, more mesh equals more foreign body response, which is not contained in the summary of opinions in the expert report, and it's an opinion that goes beyond both his expert report and the depositions I took of Dr. Guelcher.

MR. WALLACE: I would only add, Your Honor, that he filed a supplemental report shortly after that that addresses the more-mesh concept which is on Page 2 of his supplemental report --

MR. THOMAS: I thought the supplemental --

MR. WALLACE: -- which I will go get if you want me to.

THE COURT: Let's see what he's got.

MR. WALLACE: But I can tell you -- I will just wait.

THE COURT: Wait.

MR. WALLACE: Thank you, sir.

MR. THOMAS: Your Honor, I brought the Court the supplemental report of Dr. Guelcher, and Page 2 of the

supplemental report has exactly the same opinions that are in the original report.

MR. WALLACE: No, there is a -- let me get you the right report, Dave. Let me go get the right report for him.

THE COURT: Get whatever report you have.

MR. WALLACE: More --

THE COURT: That's all right. It was represented that he was not offering any new opinions on his supplemental report when I was considering *Daubert* motions.

MR. WALLACE: Your Honor, this is a rebuttal report that was done many, many, many months ago, not the matter that you addressed. So --

THE COURT: So it either was or wasn't in the report.

MR. WALLACE: It is in the report, Your Honor. I can point it to you and point it to Dave, if you'd like me to.

THE COURT: Why don't you two take a minute. I need to know the sequence --

MR. WALLACE: Sure.

THE COURT: -- because when I was ruling on the reports, as I recall, the -- the issue came up with regard to whether he was offering any new reports in supplement -- any new opinions in the supplement. And the answer I got from you all was "no."

MR. WALLACE: And that is correct, Your Honor.

THE COURT: All right. Why don't you all talk about

it, whatever this is.

MR. WALLACE: Sure.

(Discussion held off the record between Mr. Wallace and Mr. Thomas.)

THE COURT: Yes, sir.

MR. THOMAS: Your Honor, I have spoken with Mr. Wallace, and Dr. Guelcher did, in fact, supply a rebuttal report to the expert reports of Ethicon. And we did file a motion, a *Daubert* motion -- let me back up. The rebuttal report does refer to Paragraph E, more mesh equals more foreign body response. We moved on Dr. Guelcher and the Court found in the order, I have the *Daubert* order if you'd like, and limited Dr. Guelcher to the four opinions in the original report --

THE COURT: I don't remember a reference to a separate supplemental report. I remember -- give me that sheet of paper.

MR. THOMAS: I have the *Daubert* order if the Court likes.

THE COURT: Ethicon moved to exclude Dr. Guelcher's testimony as it relates to supplemental reliance material list. Did you go beyond that?

MR. THOMAS: That's a different motion -- no, Your Honor. That was a motion -- they filed a supplemental reliance list adding new documents, right before trial, that I

hadn't had an opportunity to depose Dr. Guelcher on.

MR. WALLACE: Right.

MR. THOMAS: The Court denied that motion because they were late-produced documents, as I recall the Court's order. What I'm referring to is the *Daubert* motion that we filed --

THE COURT: Let me see a copy of the opinion that you are referring to.

(Pause.)

THE COURT: Show me. Show me where I limited Dr. Guelcher's opinion. I don't recall doing that.

MR. THOMAS: Page 17 of the order, Your Honor.

THE COURT: Where is it that you moved to limit his testimony about the opinion you're talking about?

MR. THOMAS: The opinion that he's talking about here --

THE COURT: Where is it that you moved to limit that? I don't remember that.

MR. THOMAS: I understood that was part of the *Daubert* ruling, and the Court -- what I relied on is the Court specifically laid out what the opinions were going to be. The other alternative is this is not a true rebuttal opinion, but we can get to that later.

THE COURT: What I'm trying to understand -- I'm sorry. Did you object and raise an issue, when -- in your

*Daubert* motions in this particular opinion and his qualifications to offer it?

MR. THOMAS: I'm hesitant to represent that, Your Honor, because it's been a long time since I looked at the actual papers, to be honest with you, so I can't represent that to the Court.

MR. WALLACE: Your Honor?

THE COURT: Yes.

MR. WALLACE: Your Honor, you asked a question about the chronology, just so it's clear, and Mr. Thomas and I agree on this, this rebuttal report was offered before Dr. Guelcher's deposition was even taken the second time around. So we hope that it's a nonissue, we can move through quickly on the stand. In other words, he's been deposed. I just want --

THE COURT: Was he cross-examined on that opinion?

MR. WALLACE: Well, there was lots of hours of testimony by Mr. Thomas, from which Mr. Guelcher still --

THE COURT: He didn't testify, did he? I'm teasing.

(Laughter.)

THE COURT: Go ahead and finish your thought.

MR. WALLACE: No, I was just saying, Your Honor, and Mr. Thomas agrees with this, we provided this rebuttal report, Mr. Thomas and I agreed that even Mr. Guelcher can come back and be deposed a second time, and Mr. Thomas and I mutually

agreed, worked out the second deposition.

This was months and months before the *Daubert* motions were ever filed, and so I would suggest that this opinion has been out there. It's nothing new.

THE COURT: But it's not in his report.

MR. WALLACE: It is in his report, Your Honor. It is in his expert rebuttal report that he filed which is the subject of the --

THE COURT: Let's make it clear so the record is clear.

MR. WALLACE: Thank you.

THE COURT: What is the objection?

MR. THOMAS: One, it's not in his original report. When we moved on *Daubert* grounds to strike his testimony entirely, for a number of reasons, the Court found these were the four opinions which he was to express at trial. That's what I --

THE COURT: To be clear, are you saying that he did not offer this opinion before you made your motion?

MR. THOMAS: No, I'm not, Your Honor.

THE COURT: And did you move to say he wasn't qualified to offer this opinion?

MR. THOMAS: I'm sure that I did, but I can't tell you specifically that I did, Your Honor.

THE COURT: Well, I'll let the jury go take a break

and you show me what you did.

MR. THOMAS: I'm not going to be able to put my hands on it very quickly and I'm reluctant to take that much time with the jury. I don't want to do that to the Court or --

MR. WALLACE: Dave, can I offer a suggestion?

MR. THOMAS: Sure.

THE COURT: Off the record.

(Discussion held off the record between Mr. Wallace and Mr. Thomas.)

MR. THOMAS: Your Honor, I think we have reached an accommodation on it.

THE COURT: Okay. Let's go.

(Sidebar concluded.)

THE COURT: Okay. Mr. Wallace?

MR. WALLACE: Can we move to the next slide. Let's just go ahead and try to move ahead a little.

BY MR. WALLACE:

Q. Did you provide an expert report, a rebuttal report and some reliance lists in this case?

A. Yes, I did.

Q. Okay. And in those documents, did you provide certain opinions?

A. Yes, I did.

Q. Okay. And would you agree with me that the reports that you filed and the rebuttal report you filed were much more

extensive than what we have here represented on the slide?
A. Yes.
Q. Okay. Well, just to move forward, is this your summary of opinions?
A. This is my summary of opinions.
Q. Okay. And, Dr. Guelcher, before we get to the summary of your opinions, what I want to do is just establish some definitions for the jury.
And I'm going to start with, Dr. Guelcher, what is polypropylene?
A. So, polypropylene is a manmade or a synthetic material, in a chemical plant. It's based on a petrochemical, and it's produced in pellet form as shown in the picture there. And an important point about this is that polypropylene is known to be unstable, due to its molecular structure, the reactive oxygen, and so, like many other products, antioxidants are added to extend the service life of the polypropylene, to make it last longer for the application it's designed for. That's the purpose of the antioxidants.
Q. Can you tell the jury what -- some products that are made with polypropylene?
A. Well, polypropylene parts are important in automotive applications, toys, fishing line. It's a very well-known industrial chemical that's used in a lot of applications.
Q. Let's go back to your summary opinion slide,

Dr. Guelcher. It says, "Polypropylene plus oxygen equals degradation." What do you mean by that?

A. So, polypropylene will react with oxygen and degrade. This is known as an oxidation reaction. And that changes the chemical structure of the polypropylene, is the most important point. So, by reacting with the oxygen, its chemical structure is changed. It's not stable.

Q. And I first want to talk about polypropylene outside of the body.

A. Yes.

Q. Okay? So, when you're talking about polypropylene reacting with oxygen equalling degradation, are you referring to polypropylene outside of the body?

MR. THOMAS: Your Honor, objection, leading.

THE COURT: Sustained, but you can ask it directly pretty easy.

BY MR. WALLACE:

Q. What happens to polypropylene out of the body?

A. Outside of the body, polypropylene can react with oxygen, molecular oxygen just in the air that we breathe, O2. This is a faster reaction rate at higher temperatures, so in order to make polypropylene useful, we saw the pellets. A pellet's not very useful. So what you'll do is you'll heat it up and either extrude it or mold it, but you have to heat it to high temperatures in order to process it into a useful part. And

these oxidation reactions can become very important at those conditions.

Q. Let's just try to march through these, and then maybe we'll come back to a few of them.

Number -- I'm sorry, Letter B, it says, "Antioxidants can slow down degradation, but they cannot prevent it." What do you mean by that?

A. So, this relates to the concept of a service life. So, just about anything that you make or buy has a -- it's useful for a certain period of time. Then it wears out. And the same applies to plastics. And so antioxidants can slow this degradation process, these chemical changes, for a period of time, they can extend the service life, but they can't prevent it forever. This process will continue, and eventually these changes will happen. The question is when.

Q. When you talk about changes, are you talking about the degradation process?

A. Yes. Changes to the structure of the molecule, of the polypropylene.

Q. How long has this been known in the chemical field, Dr. Guelcher?

A. Since the 1960s. When polyurethane -- polypropylene was first invented, it was noticed that it had these degradation problems, and that's when scientists started adding antioxidants to make it last longer.

Q. Let's move on to C. It says, "The body's natural defense mechanism -- the foreign body response -- attacks the polypropylene."

Let's take those one at a time. Dr. Guelcher, what are you referring to when you say "the body's natural defense mechanism"?

A. So, this is the response that your body has when a foreign material is implanted, the material that your body knows is not part of your body, and there's a defense mechanism that the body has to deal with this to reject it or to destroy it, and this is essentially the natural defense mechanism.

Q. What do you mean by -- could you give us an explanation of "foreign body response," or is that what you just --

A. So, the foreign body response or the foreign-body reaction is a scientific term that's used to explain this defense mechanism. So, there's a reaction that happens when a foreign body is implanted at the cellular level, so this happens actually to specific cells that attack the material. That's what I'm referring to by the foreign body reaction. It's just this natural defense mechanism.

Q. Dr. Guelcher, "attack" seems like a pretty strong word, so could you explain that to the jury?

A. So, cells in your body, known as inflammatory cells, these would be things like white blood cells, macrophages,

foreign-body giant cells, these are inflammatory cells that their job is to attack the foreign body.

A simple example would be a bacterial infection. Bacteria is not supposed to be there, and so there's specialized cells in the body that attack that and try to destroy it so it doesn't harm the body. That's the response.

Q. Letter D says, "The foreign body response will not stop until the mesh is removed." Do you see that?

A. Yes.

Q. And what do you mean by it?

A. So, the mesh is a foreign body. It -- it's not naturally in your body. Like I said, it's a synthetic polymer that's made in a chemical plant. It's planted in the body to accomplish a certain purpose. And the body recognizes it as a foreign material, and it will continue to attack it in this way until it's removed or destroyed or it's gone.

Think of a splinter that you get in your finger. If you never remove it, it over time will extrude. It's a simple example, but that's the idea. It's ongoing until the foreign body is gone.

Q. And you use the word "mesh." What are you referring to?

A. I'm referring to the polypropylene Prolene mesh that we're discussing here today.

Q. When you say, "More mesh equals more foreign body response," what do you mean?

A. So, this is sort of a logical consequence of the other opinions, in that if you have more mesh present -- this is happening at the surface of the material, at the surface is where it's happening. If you have more mesh, well, you're going to have more response. It's going to be an elevated response. More cells, more reactive oxygen, more -- it's an elevated response, yeah.

Q. Well, you talked about more reactive oxygen and gave a couple of other words that I think we're going to need to define.

A. Yes.

Q. But why don't we try to go, just keeping moving through it, and we'll come back to that.

Next slide. Keep going. Okay. What -- first of all, before we get into the structure here, what are you trying to explain to the jury?

A. So, this slide is explaining how this reaction that's known as oxidation -- oxidation is a reaction with oxygen -- how this oxidation reaction alters the structure of polypropylene. So you start off with the structure of polypropylene, and you end up with something that's different. That's the purpose of this slide.

Q. And so on the left, does that represent the chemical --

A. So --

Q. Let me -- excuse me, Doctor.

A. I'm sorry.

Q. I'm sorry, let me finish.

Let me ask it this way: What is the box on the left?

A. Okay. So the molecule on the left is the structure of polypropylene. That's a unit that repeats, so it's a very long chain of these units. And the box in red, that's the carbon-hydrogen tertiary bond. Why is it a tertiary bond? Well, that carbon is bonded to other carbons, except for that hydrogen. That's why it's a carbon-hydrogen tertiary bond. So this is kind of the chemistry concept.

So -- and that bond is vulnerable to attack by the oxygen. That's where the attack is happening. And there is a series of reactions in this step that lead to changes in the polypropylene structure, but that particular bond is the one that reacts.

THE COURT: Hold just a second. It's not usual, just so the jury knows, it's not usual for me to be showing you things on here that the witness hasn't first tried to explain or -- and I have a series of slides, it appears.

Have you had an opportunity to review them?

MR. THOMAS: I'm looking at them right now, Your Honor.

THE COURT: What I want -- what I want to do is not put them up until I see if there's an objection.

MR. WALLACE: Sure, Your Honor. I didn't realize --

THE COURT: So before you get ready to go to your next one, we'll see it.

MR. THOMAS: I have no objection to the next one, Your Honor.

THE COURT: All right.

MR. WALLACE: Okay.

THE COURT: If we could just keep that process up, I would appreciate it.

MR. WALLACE: And going forward, that will absolutely be the case, Your Honor.

THE COURT: Thank you.

BY MR. WALLACE:

Q. When you said "vulnerable to attack," can you just tell the jury what concept you're trying to explain?

A. There's a reaction between the oxygen and that bond.

Q. What's the next red box represent?

A. So, the next red box shows how that bond changes, so you start off with this tertiary carbon-hydrogen bond. The next red box shows that bond turn into what's called a hydroperoxide bond, so it changes. Its chemical structure changes. That's what's denoted there.

Q. When you say "chemical structure changes," you're saying that the polypropylene actually changes because of oxidation or something else?

A. Yes. It's a different molecule now, because you have

this hydroperoxide group instead of the hydrogen that's changed.

Q. And we talked a little bit about antioxidants already. But why don't we look at that second bullet point, where it refers to structural changes. Can you tell the jury what you're trying to say there?

A. So, these changes in the structure, for example, the carbon-hydrogen bond going to a hydroperoxide bond, that could be measured using analytical techniques such as spectroscopy, so we could measure that, we can measure that change, and we can also measure the change in the following reaction when it goes to a carbonyl, which is the last red box. That's another chemical change that we can measure by different analytical changes.

Q. When you say "we," who are you referring to?

A. Scientists, engineers.

MR. WALLACE: Let's go to the next slide, please.

MR. THOMAS: That's fine.

MR. WALLACE: Okay. Thank you.

BY MR. WALLACE:

Q. You say at the top, "Implant materials selection." And at the top you have "polypropylene," and then you have an arrow. What do you mean?

A. So, this slide is showing several different types of materials, and how easily they are oxidized or how easily this

reaction with oxygen can occur. And so at the bottom, where it says, "Difficult to oxidize," these are materials that react very slowly with oxygen. For example, Teflon, Teflon reacts slowly with oxygen.

Polypropylene, on the other hand, is one of the more easily oxidized materials. So it's reacting much faster with oxygen than a large number of other materials. It's much more easily oxidized in that respect.

Q. How long have chemical scientists like yourself known that polypropylene is easily oxidized?

A. This has been known for decades, I think. Since the 1960s, it was known that polypropylene is easily oxidized.

MR. WALLACE: Can you go to the next slide, please. Dave --

MR. THOMAS: That's fine.

MR. WALLACE: Thank you.

BY MR. WALLACE:

Q. All right. You've talked a little bit about foreign body reaction. You've got some photos here. Can you take us through them?

A. So I mentioned the foreign-body reaction earlier. This is the body's response to something that's implanted. It's caused -- it's called the foreign-body reaction because that refers specifically to the types of cells that respond. So it's a reaction. You implant the material, and certain cells

respond.

And so these are polyurethane films that were in the body, and it shows the progression of this reaction. So in the upper left-hand corner it says, "Monocytes, zero days," so very quickly after an implantation of the device, or this material, this foreign body, monocytes, which are very small mononuclear cells, they have one nucleus, they attach to the surface. They recognize it as a foreign body and they attach. And that's what starts off this reaction.

Now, as you see the arrow there, it points to macrophages at three days. Then these monocytes over a period of several days change to form another cell called "macrophage." And it's important to remember these cells are attached to the surface. They're what we call an adherent cell. They're attached to the surface of the material.

And then after about a week, some of these macrophages will fuse. That means they join together to form a great big cell that has multiple nuclei instead of just one, and then finally, after about two weeks, that FBGC 14 days, those are called foreign-body giant cells. That's just what they are, they're giant cells, they're very large cells that have multiple nuclei. And, again, all these cells are adherent to the surface.

So, what happens at the surface is they're secreting what's known as reactive oxygen species. And this is oxygen

that's -- these are oxygen species that are much more reactive than molecular oxygen, so they're much more potent. They react faster. And that material surface is exposed to these species. So it's exposed to these oxidizing agents.

This is what's known as the foreign-body reaction. But it's driven by these types of cells that attach to the surface and secrete reactive oxygen species with an aim to destroy the material. That's why they're there. They want to remove this material because it's a foreign body.

Q. Okay. So, if I understand you correctly, the monocytes work with the macrophages to combine the foreign-body giant cells and adhere to the surface of a foreign body; is that right?

A. Yes, they're adherent, yes.

Q. All right. Going back to this "attack" word that you used, is that what you're describing there?

A. This is the scientific explanation of the word "attack." It's a chemical attack. It's, again, reactive oxygen species or ROS.

Q. What are the -- what are these foreign-body giant cells actually tying to do to the implant?

A. Well, they're trying to remove it from the body. That's the response, to destroy it.

Q. What does ROS do in the body? What function does it serve?

A. So, much like if you take polypropylene and you heat it in the air, your source of oxygen in the air is molecular oxygen that we breathe, so if you heat it up, that molecular oxygen in the air will react.

Well, in the body, it's a much lower temperature. So you don't have this thermal oxidation, at high temperatures, but the reactive oxygen species serves the same purpose. They're much more reactive than oxygen at the body conditions, and so they can cause these changes to polypropylene because of their high reactivity.

Q. Dr. Guelcher, if I heard you correctly, are you offering an opinion that reactive oxidative species is actually -- has -- is stronger than the oxygen --

MR. THOMAS: (Stands.)

THE COURT: Sustained.

BY MR. WALLACE:

Q. What effect -- let me ask this question: Does ROS have an effect on polypropylene implanted in the human body?

A. Yes, it does, because polypropylene reacts with oxygen. This is simply a much more potent form of oxygen, so it's a similar reaction.

Q. Thank you.

And how long has the foreign-body reaction been understood by scientists and biomedical engineers like yourself?

A. So, this was discovered in the early 1990s in a few very important papers. It was discovered that the failure of certain biomaterials could be traced in this foreign-body reaction. So materials that were thought to be safe, such as insulation and cardiac pacemaker leads, thought to be safe, but in the early 1990s, we realized that, in fact, it wasn't because this foreign-body reaction was causing it to degrade. That's what -- so it was in the early '90s.

MR. THOMAS: This is the polyurethane slide?

MR. WALLACE: Okay.

MR. THOMAS: Yes.

MR. WALLACE: Okay. We'll just go to the next slide.

BY MR. WALLACE:

Q. Can you describe to the jury what you have done with this slide? And can I withdraw the question and ask you a different one?

Did you actually create this slide yourself?

A. Yes, I did.

Q. Okay. So, tell the jury what you're trying to explain there.

A. So, I spent some time talking about the foreign-body reaction. And this happens no matter what you implant. Even it can happen with other types of dead tissue. It -- it happens with anything you implant into the body.

The important question as an engineer, someone

designing a material, is: How is the material that I'm implanting going to respond to that foreign body reaction? That's something I can control, as an engineer, and it's a very important question.

So, here I'm using the example of the poly(ether)urethane pacemaker lead to explain this point.

And so these were, again, materials that were believed to be safe, and then some patients started having problems and the leads were taken out of the body or explanted, and some studies were done, and it was shown that the combination of chemical degradation that results from the foreign-body reaction, that's the reactive oxygen, causes chemical degradation, just like I explained for polypropylene. That combined with physical damage such as cracking, in response to this, embrittlement, led to device failure in a number of patients, so it can be a very serious problem. And it doesn't stop until the device is removed. And this has led to the discovery of replacing materials for this application.

So, in this little chart here, I tried to show what I consider to be really a vicious cycle of this problem. So if you look at the bottom, when the device is implanted, you have this infiltration of inflammatory cells, that's at the bottom. And that happens once the device is implanted. So you get these cells that attach to the surface, and then oxidation, that's in response to the reactive oxygen secreted by the

cells.

So, now we have oxidation of the material or reaction, it's changing, it becomes embrittled. This can result in loss of flexibility, cracking, which leads to more exposed surface. So this reaction starts at the surface and it keeps going down into the bulk of the material, can result in mechanical failure. So this is the effect that the foreign-body reaction can have on an implant that's not resistant, that's not -- that is susceptible to reaction with oxygen. That's what's summarized in this slide.

Q. Dr. Guelcher, have you -- are you aware of any instance where degradation might be desired in an implant?

A. So, in my own research at Vanderbilt, these are some papers we published just in the past few years. And we're interested in a different problem, that is, if I have a bone void and it's not healing, can I put a scaffold in there or a graft that will help it to heal. In other words, it won't heal because there is a large hole, but if I put a structure that has a scaffold to it, cells can migrate in and heal it.

Now, in this application, we want that scaffold to go away once the wound is healed, but it's very important that we control the rate at which it goes away. So we've actually designed materials that respond to this foreign-body reaction, in other words, they are designed to go away once cells start to cause a new matrix, they degrade the scaffold, and the end

result of this process is you have a healed wound.

So we're actually using this foreign-body reaction to design new materials that will improve healing. That's quite different from the polypropylene case where you want it to be stable. That's a very different application. But my point is that we can -- as an engineer, we can actually design materials that respond to this foreign-body reaction, to accomplish healing. That's the work that I'm doing now.

Q. I want to make sure I've heard you correctly, going back to whether or not the process ever stops. Is there any time that the reactive oxidative species will stop attacking the mesh?

MR. THOMAS: Asked and answered, Your Honor.

THE COURT: Sustained.

BY MR. WALLACE:

Q. Does polypropylene degrade inside the human body?

A. Yes, it does.

Q. Can you explain that to the jury?

A. It's the same process of attachment of inflammatory cells that then secrete reactive oxygen, the polypropylene reacts with that oxygen, and the composition changes.

Q. When you use the word "embrittlement," what do you mean?

A. So, "embrittlement" is a technical term that refers to the transition from a plastic that starts off being very compliant or stretchy, you can pull on it like a rubber band,

and it becomes more brittle, so it's -- then it's like a hard, rigid plastic. It's hard, it's rigid, it cracks. That's what we mean by "embrittlement."

Q. Do you have an opinion on whether polypropylene becomes embrittled inside the human body?

A. Yes. So, the consequence of this response to the foreign-body reaction is embrittlement. That's one consequence, that's one response.

Q. Do you have an opinion on whether polypropylene suffers from a loss of flexibility inside the human body as a result of embrittlement?

A. Yes. So, loss of flexibility would happen when it becomes brittle. It's no longer compliant or stretchable.

Q. We talked earlier about antioxidants.

MR. WALLACE: Can we go to the next slide?

MR. THOMAS: Yes.

BY MR. WALLACE:

Q. Can you explain to the jury the reason for this slide?

A. So, as I mentioned before, because of the susceptibility of reactivity of polypropylene with oxygen, we have to add antioxidants. And these are typically packaged as primary and secondary antioxidants, and this technology, again, was worked out largely in the 1960s.

So, what do I mean by "primary" and "secondary"? Well, a primary antioxidant is one that is intended to protect it

while it's being processed at high temperatures. So you have a pellet, and you want to make something useful out of the pellet. You have to heat it up and remold it. This requires high temperatures, and so these antioxidants are designed to protect while it's being processed at high temperatures, and some of them are expended, at this time. They're consumed, they're used up.

Now, a secondary oxidant essentially enhances the primary one. It's intended to improve long-term storage. It's intended to protect against ultraviolet light. So different antioxidants do different things and they're used in combinations that have an overall good effect to stabilize it.

Q. Why is that important to you, as an expert in biomedical and chemical engineering in this case?

A. Well, the question that I would have is these antioxidants are designed to protect during processing and during long-term use, exposure for several years to summers in Tennessee, for example, but they're not optimized to protect polypropylene against this reactive oxygen in vivo.

Q. Dr. Guelcher, can I interrupt you there?

A. Yes.

Q. What do you mean by that?

A. Well, they are not designed or they not intended to protect polypropylene against this reactive oxygen, against this foreign-body reaction.

Q. What do you mean by "intended"?

MR. THOMAS: Objection, Your Honor, testifying to the state of mind of Ethicon.

MR. WALLACE: I'm not talking about Ethicon, Your Honor. I'm asking --

THE COURT: Overruled. Go ahead.

THE WITNESS: So the purpose of the antioxidant is to protect against processing at thermal -- sorry -- processing at higher temperatures, long-term exposure to atmospheric oxygen that we breathe. Its purpose is not to protect against reactive oxygen in vivo. It's not possible because the reactive oxygen, foreign-body reaction, wasn't discovered until 1990.

So these antioxidant packages, when they were created, they simply didn't know about the foreign-body reaction, so this wasn't taken into account when they were designed.

BY MR. WALLACE:

Q. Do you know whether or not -- well, why is that important to the TVT-O device?

A. Well, because it's -- it's not guaranteed that these antioxidants are going to protect against the reactive oxygen in the body. It's not been studied. It wasn't looked at. It wasn't taken into account when these devices were designed.

Q. Do you know whether or not the Prolene mesh that is the

TVT-O mesh, do you know whether or not that has an antioxidant package added to it?

A. So, Prolene has this package of secondary anti- -- primary and secondary antioxidants. It has a primary antioxidant, this is what's referred to as a hindered phenolic compound. What that means is it reacts with free radicals, and it doesn't evaporate when you heat it to high temperatures, it stays in the material, it doesn't evaporate into the air.

It also has a secondary antioxidant which is a typical one that's used. This is a thioester and, again, this is intended to improve long-term storage at atmospheric conditions, not in the body, but atmospheric conditions.

Q. Do you have an opinion on whether the antioxidant package that is added to the Prolene mesh that is the TVT-O stops degradation?

MR. THOMAS: Objection, Your Honor. Sidebar, please.

THE COURT: Hold just one second.

All right. Let's see you at sidebar.

(The following occurred at sidebar.)

MR. THOMAS: Your Honor, Ethicon objects to the question as phrased because not only is it an opinion that is not expressed in the four, now five, which he's been permitted to testify, but he has not done any testing and analysis with respect to Prolene specifically to give an opinion about the

extent to which the antioxidants in Prolene would deplete over time and lead to degradation.

MR. WALLACE: Your Honor, if I were to respond, I would say it would be comprised within Opinion 1, and Mr. Guelcher, as I understand it, has been extensively questioned by Mr. Thomas on the antioxidant issue here in connection with his opinion about 1.

THE COURT: Excuse me.

(Pause.)

THE COURT: It is not listed precisely, but it was explained by you and included in the opinion. There was an extensive explanation about the evidence. What's your point? I'm sorry.

MR. THOMAS: I'm trying to understand the ruling. The witness has not done any testing to determine the extent to which the antioxidants may deplete over time.

THE COURT: He has not and he is not --

MR. THOMAS: (Indicating.)

THE COURT: Don't shush me.

MR. THOMAS: I'm sorry. That's a mannerism, not a shush. I apologize.

THE COURT: He has not. I didn't understand the question to be, had he done testing. Was that the question?

MR. THOMAS: That's the objection, to him giving that opinion as phrased because there is no basis in science or no

testing to say, to a reasonable degree of certainty, that the Prolene, polypropylene mesh, leaches antioxidants or depletes antioxidants over time so it would degrade.

THE COURT: I'm going to allow him to testify and be subject to cross-examination.

MR. WALLACE: Thank you, Judge.

(Sidebar concluded.)

BY MR. WALLACE:

Q. Dr. Guelcher, with the indulgence of counsel, I just want to go back and reorient us to where we were. We were talking about the polypropylene antioxidants that are added during the manufacturing process to the Prolene mesh. Is that correct?

A. That's right.

Q. Okay. And, just to get us back to where we were, you said that, if I'm correct, you had an opinion on whether or not those antioxidants that are added to the Prolene mesh stopped the mesh from degrading. Is that right?

A. Yes.

Q. Okay. Can you explain why it is, why is it your opinion that the antioxidant package that's added to the Prolene mesh, that is ultimately made into the TVT-O, does not stop degradation?

A. Well, I've seen evidence that Prolene sutures undergo this reaction with oxygen and showed evidence of surface cracking. Based on that evidence that I've seen, I don't

believe these antioxidant packages stabilize polypropylene against ROS in vivo, in the body.

Q. And what specifically -- what evidence are you specifically referring to?

A. There were -- there are two studies that I've reviewed. One was a study in dogs where these sutures were followed up to seven years, and the other is studies of sutures that were explanted from human patients for up to eight years. That's the evidence.

MR. WALLACE: 2026, Dave.

MR. THOMAS: Do you have a copy for me?

MR. WALLACE: I'm sorry.

MR. THOMAS: Thank you.

MR. WALLACE: Your Honor, I was able to talk to Mr. Thomas during the break about the four documents we'll be referencing.

THE COURT: Yes.

BY MR. WALLACE:

Q. So, Dr. Guelcher, you've -- do you have Exhibit 2026 in front of you?

A. Yes.

Q. Okay.

MR. WALLACE: Dave -- I'm sorry, counsel, do you have it?

MR. THOMAS: I do, thank you.

MR. WALLACE: Okay.

BY MR. WALLACE:

Q. Is this one of the studies that you're referring to?

A. Yes.

MR. WALLACE: Your Honor, may I publish it on the screen?

THE COURT: Do you want to move its admission?

MR. WALLACE: Well --

MR. THOMAS: I have no objection, Your Honor.

THE COURT: It may be received.

MR. WALLACE: Thank you, Your Honor.

(PLAINTIFFS' EXHIBIT P-2026 WAS RECEIVED IN EVIDENCE.)

THE COURT: Make sure that the paper copy is provided to the Courtroom Deputy -- after. You don't have to do it this minute. But just be sure.

MR. WALLACE: Thank you.

BY MR. WALLACE:

Q. And what is in front of you, Dr. Guelcher?

A. So, this is a document explaining the analysis of Prolene sutures that were explanted from humans.

Q. And if you look at the top of the left-hand page, where it says, "IR microscopy of explanted Prolene." Do you see that?

A. Yes.

Q. In your review of this study, what does that mean to you?

A. So, IR is infrared, spectroscopy, and infrared spectroscopy is useful for identifying specific chemical bonds in the material, so it tells us what bonds are there. And this is a spectroscopy technique that's used to assess that.
Q. And do you know whether or not this is an Ethicon study?
A. Yes, it has Ethicon letterhead on it, so this was --
Q. And do you -- do you know the date that this document was published?
A. So it's September 30th, 1987.
MR. WALLACE: Can you pull that up and also the "Samples" paragraph at the top?
BY MR. WALLACE:
Q. When you said that it was a human -- that it came from a human, if you can look at that language and explain to the jury what they're seeing.
A. So, this is a human vascular graft, that's a blood vessel graft, that was explanted -- that means it was taken out of a human -- by this Professor Guidoin in Quebec, I believe, and examined by IR spectroscopy.
Q. And if you could go to Page 2 and look at the conclusions, please.
Tell us, Dr. Guelcher, what you found significant about the conclusions in this Ethicon study.
A. So, the first conclusion states that the amount of DLTDP, that's a secondary antioxidant -- that's the secondary

antioxidant that's used in Prolene -- is reduced in the explanted sutures. So no DLTDP is observed in the surface scrapes, so there were cracks on these regions that they scraped. They didn't see --

Q. Can we stop there for a second --

A. Yes.

Q. -- so we can take it one step at a time, Dr. Guelcher.

When you say "DLTDP," are you referring to the antioxidant?

A. Yes, that's the antioxidant.

Q. And can you explain in practical terms what the significance of this conclusion is as it relates to your opinions?

A. Well, the way I interpret this statement is there are cracked regions, so, again, this foreign-body reaction can lead to cracking, embrittlement, because brittle things crack. These cracked regions show no evidence of this stabilizer, so that means that the stabilizer is expended, it was used. It was used up in this region. And once it's used up, there's nothing to protect the polypropylene from reacting. So it tells me that the antioxidant in this cracked region was consumed and that the polypropylene had oxidized. This is what this tells me.

THE COURT: May I interrupt just a second? This is 1987. I thought you said they didn't figure this out until

the '90s.

THE WITNESS: Well, sir, I meant that the foreign-body reaction wasn't discovered until the '90s, but this was an observation that was made independent of that discovery.

THE COURT: What's the difference?

THE WITNESS: Well, so the discovery in 1990 was why this happens. So there were a number of observations in the '70s and '80s that this was happening. And it wasn't until the 1990s where it was explained on sort of a cell and molecular level what exactly was happening. This is an observation.

THE COURT: Proceed.

MR. WALLACE: Thank you, Your Honor.

BY MR. WALLACE:

Q. With respect to Conclusion Number 2, what is the significance of Conclusion Number 2 to your opinion of -- on whether or not the antioxidants stop the degradation process?

A. Well, I think Number 2 is consistent with Number 1, in that these cracks cannot be attributed to protein or tissue that's sticking to the material. It's not material from the body. It's cracked polypropylene, oxidized polypropylene. So this is consistent with the notion that the antioxidant was consumed and the polypropylene had reacted.

Q. What -- with respect to the word "protein" in these kinds

of studies, what are they referring to?

A. Well, protein would be -- it's a component of tissue. So tissue from the body, this is essentially, in my interpretation, saying that there's no tissue that's stuck to these sutures. It was successfully cleaned, and what you're looking at is the polypropylene. You're not looking at tissue that's stuck.

Q. Thank you.

Can we just move to 3 then, please.

What's the significance of Conclusion Number 3 to your opinion, Dr. Guelcher?

A. So, Statement Number 3 is again saying there are these cracked regions of the suture, where we see cracking, that was scraped off, and that scraped-off material that had cracked, they did an experiment to measure at what temperature does it melt. So we know that pure polypropylene melts at a certain temperature, and this material melted at a temperature below that, so that's a change in the melting temperature. That tells us there's a change in the polypropylene because pure polypropylene melts at a specific temperature just like, you know, ice melts at zero degrees, you know, zero degrees Celsius. Ice melts at a defined temperature.

In the same sense, polypropylene melts at a very defined temperature as determined by the structure, and if that structure changes, the melting temperature will change,

and that's what was seen here. So there's a change in the melting temperature that's consistent with this notion that it oxidized and changed.

Q. What effect, if any, does Paragraph Number 4 have on your opinions?

A. Well, I find Paragraph Number 4 to be a subjective statement. Again, this reaction starts at the surface and works its way down. And some of the cracks -- I mean, again, it's happening at the surface, and to say that it's only a minor portion of the entire suture, I think that needs to be tested further.

Q. Do you know whether or not there were any images taken of these -- of this polypropylene?

A. From my understanding, there were, yes.

THE COURT: Where did you get that idea?

THE WITNESS: From the report.

THE COURT: All right.

THE WITNESS: Sorry. I'll be more direct.

THE COURT: I was just trying to see if there was a foundation to be laid here.

MR. WALLACE: Sure. 2026, any objection, Dave?

MR. THOMAS: Yeah, there is. I need to approach with counsel on this.

THE COURT: Okay.

MR. WALLACE: We'll try to work it out ourselves.

THE COURT: All right. 2026, when it's finished -- go ahead and bring her 2026 so we won't get behind here. All of this has been about 2026.

MR. WALLACE: Thank you.

THE COURT: Got it worked out?

MR. WALLACE: I hope so. I believe so.

THE COURT: All right.

MR. THOMAS: That's my -- I'm sorry.

THE COURT: I'm sorry.

MR. THOMAS: That's my copy, I think you took.

(Laughter.)

MR. THOMAS: Got to have a program.

THE COURT: All right, Mr. Wallace.

BY MR. WALLACE:

Q. Dr. Guelcher, I made a mistake. When I spoke about the SEM image, images that you might have seen, I linked them to this human study. So I'm going to make my question really simple and very clear for the record.

Have you seen any Ethicon documents where there are SEM images of Prolene explants?

A. Yes.

Q. Okay.

MR. WALLACE: 14461 is the exhibit I'd like to offer, Your Honor, and move it into evidence at the conclusion of the case, absent counsel's position on it.

MR. THOMAS: Your Honor, these are just kind of SEM images in the air. They're not tied to anything. They're scanning electronic microscopy images that aren't tied to anything, and I don't think there's an adequate foundation for them to be --

THE COURT: This time I have to sustain the objection.

MR. WALLACE: That's fine. Thank you, Your Honor.

BY MR. WALLACE:

Q. You mentioned a dog study. Can you tell me whether or not you reviewed any Ethicon documents relating to a dog study and whether -- I will just leave it there.

A. Yes, I did.

Q. Okay. And did you review those documents in connection with reaching your opinions in this case?

A. Yes, I did.

MR. WALLACE: 13152 would be the exhibit I'd like to offer, Your Honor, absent an objection.

THE COURT: Is there an objection?

MR. THOMAS: No, Your Honor.

THE COURT: It may be received.

MR. WALLACE: Thank you, Your Honor.

(PLAINTIFFS' EXHIBIT P-13152 WAS RECEIVED IN EVIDENCE.)

THE COURT: Make sure there's a paper copy provided to the Courtroom Deputy.

MR. WALLACE: Can we pull up --

THE COURT: And provide it to the Courtroom Deputy.

BY MR. WALLACE:

Q. Can you please -- do you have it in front of you, Dr. Guelcher?

A. Yes.

Q. Can you tell the jury what the document you have in front of you is and the document that they have on the screen in front of them?

A. So this is titled "Seven-Year Data for a Ten-Year Prolene Study."

Q. And what is the date of that?

A. October 15th, 1992.

Q. And, in reviewing this document in connection with the work that did you in this case, what conclusions did you draw?

A. Well, this document, again, showed evidence that the polypropylene was changing and cracking on the surface of the suture, that the Prolene suture was changing with time and cracking.

Q. In the interest of time, Dr. Guelcher, I want you to look at the conclusions that are found on the second page in the middle of the document.

A. Yes.

Q. And I'm just going to take those, again, one at a time.

Can you -- and you have reviewed the entirety of this

document?
A. Yes. It's very long. Yes.
Q. Can you tell me what impact that first bullet point that's the conclusion there had on your opinions in this case?
A. The seven-year in vivo results generally substantiated the five-year findings. They closely correspond to the observations of the explanted sutures of the dog that died prematurely, and these findings were that the Prolene was cracking with time and that was increasing with time.
Q. I'd like just -- just to take a step back and give the jury a little bit of context for this study. What do you understand the study, this study to be about and how long it went?
A. So, from my reading of the document, this study was designed to be a ten-year study in dogs, to understand the stability of the Prolene suture. So what happens -- how does the Prolene suture change over time, and it's implanted in a dog because this is -- we can do this in animals. You can't do these type of experiments in humans, and the dog is a good model, it's a large animal model. And so we can use these data to tell us something about how Prolene sutures would respond and how stable they are, how they'll react in a human.
And, again, it was designed to be a ten-year study. One of the dogs died prematurely, not related to the suture, at six years and ten-and-a-half months, and so they sacrificed

all the dogs at seven years so they could get the data. That's my understanding.

Q. And let's move on to the second bullet point. Tell me what, if anything, this second conclusion -- what impact, if any, it had on your opinions.

A. So the second conclusion states that degradation in Prolene is still increasing, and PVDF, which is another material that is less susceptible, so it's less reactive with oxygen, PVDF was more stable, in terms of cracking. So my -- what I learned from this was that, with the increased time, the degradation of Prolene is continuing. This is consistent with the idea that the foreign-body reaction doesn't stop. It just keeps going until the material is removed.

Q. Can you move on to the third conclusion and tell the jury, what, if any, impact that had on your opinions in this case?

A. Well, this is, again, noting that this reaction starts at the surface, so the eight explanted Ethilon sutures all showed heavy cracking, in many cases abrasion of the dyed surface layer. A decrease in the suture diameter was apparent in several cases. So Ethilon is a different type of material. It was also degrading. And they noticed a decrease in the diameter of the suture which, again, is consistent with this idea that it starts at the surface and works its way in, until you're gradually losing material until it works its way to the

middle of the suture.

Q. Just a point of clarification, Dr. Guelcher. Are -- PVDF, that's not Prolene, is it?

A. No, that's a different material. That's polyvinylidene fluoride. That's chemically different from polypropylene.

Q. Thank you.

Let's just move right on to the fourth bullet point. And tell the jury what impact, if any, that had on your opinions in this case.

A. Well, in this other type of material, they did not find any cracks. There were some scratches. What this tells me, that these four materials that they implanted were all degrading at different rates. Some of them were more affected by the reactive oxygen than others.

Q. Is Novafil polypropylene?

A. No.

Q. How -- how have the human Prolene suture study and this dog study, how have they impacted your opinions on mesh, if at all?

A. So, both the human explants that were explanted from humans out to eight years and the seven-year dog study both show that the polypropylene, the Prolene polypropylene, reacts with the oxygen that's secreted by these inflammatory cells and it changes the structure over time. So, as we progress from one to five, seven, eight years, these changes get more

severe, we see more cracking, more oxidation, more changes in the properties of the polypropylene.

This is basically happening because of this foreign-body reaction. And, in my opinion, these changes, because the mesh is also made from propylene, this reaction with oxygen, these changes in the surface will also occur with the mesh because it's made from the same base material, propylene.

Q. So, I'll try to ask it this way, Dr. Guelcher. Does the fact that this is a Prolene suture affect at all your opinion on what you referred to as the more-mesh opinion?

A. So, I think it's very important to remember that a suture implanted under the skin or in a blood vessel is very different than mesh implanted in the pelvic floor. Mesh has a lot more polypropylene, a lot more Prolene, a lot more surface, that can react with this oxygen.

So, I think what we can learn from the suture study is that the Prolene is unstable and it reacts in the body. Whether -- in this -- in my view, would lead to more studies with the mesh actually in the anatomic location where I want to use it, in the pelvic floor.

How does this oxidation affect the mesh in the pelvic floor? This is, to me, an important unanswered question. But what these studies point to is that Prolene does change over time. That's my conclusion.

Q. Well, since we're talking about Ethicon documents, beyond the documents that the jury has seen and that have been offered into evidence, did you review any other Ethicon documents?

A. I reviewed a number of other Ethicon documents. These are the two that struck me as the most -- in forming my opinions.

Q. And in reviewing those Ethicon documents, did you see any other studies like these that were actually done on the TVT-O mesh or mesh of any kind?

A. There are a number of other studies looking at mesh, complications of mesh, and what happens to mesh when it's implanted in the body.

Q. Well, my question is more specific than that, Dr. Guelcher.

My question is, specifically, in all of the internal company documents that you reviewed, did you see whether or not Ethicon ever did any sort of explant studies on their mesh?

A. I haven't seen those documents, no.

Q. Is that at all important to you as a biomedical engineer and how it might impact your opinions in this case?

MR. THOMAS: Objection, Your Honor.

THE COURT: Sustained.

BY MR. WALLACE:

Q. Now, when you looked at these Ethicon documents, who provided those to you?

MR. THOMAS: I'm going to object to the generic description of documents. I really don't know what he's talking about. I don't think the witness does either.

THE COURT: Sustained. The documents that have been admitted into evidence, you may inquire about certainly.

MR. WALLACE: Thank you.

THE COURT: I'm not trying to limit you. I'm just trying to hurry it.

MR. WALLACE: Okay. Sure. Then why don't I move on.

BY MR. WALLACE:

Q. Did you -- in connection with the work that you've done on polypropylene, have you reviewed any literature?

A. Yes. There is a number of published papers on these meshes and how they respond.

Q. In connection -- are you familiar with Drs. Costello and Clavé?

A. Yes.

Q. Have you reviewed their work?

A. Yes, I have.

Q. Can you tell the jury -- can we go to the --

MR. THOMAS: Before you publish anything, may I have a copy of whatever you're going to publish?

MR. WALLACE: It's in the PowerPoint.

MR. THOMAS: Well, it's quotes from the study. I object to this, isolated quotes from the study, Your Honor, as opposed to the full study.

THE COURT: Do you have a copy of the full study that you can provide counsel? If that's what you plan to introduce.

MR. WALLACE: It's just the articles. They're marked as exhibits. I'll give you the exhibit numbers, David. I believe you have a copy in front of you.

THE COURT: Why don't you two get together.

MR. WALLACE: Sure.

THE COURT: Maybe over that way a little bit.

(Discussion held off the record between Mr. Wallace and Mr. Thomas.)

MR. WALLACE: Your Honor, may I proceed?

THE COURT: You may.

MR. WALLACE: And, Mr. Thomas, you have the article.

BY MR. WALLACE:

Q. In connection with your work, did you perform a literature search?

A. Yes, I did. I searched a number of papers on this.

Q. And in connection with your work, did you come across any articles that dealt with polypropylene degradation in explants?

A. Yes, I did.

Q. And what articles were those?
A. Well, I've selected three that I believe make the point, by Clavé, et al., and published in 2009; by Costello, et al., published in 2007; and by Wood, et al., published in 2013.
Q. And, for the record, the Clavé article is Exhibit 21457.
A. Yes, that's right.
MR. WALLACE: And absent an objection, I'd like to be able to publish it to the jury.
THE COURT: 21 -- the number is?
MR. WALLACE: 21457.
THE COURT: 21457 may be admitted when presented to the Courtroom Deputy.
(PLAINTIFFS' EXHIBIT P-21457 WAS RECEIVED IN EVIDENCE.)
MR. WALLACE: Thank you.
Your Honor, as a learned treatise, we'd -- it's my understanding we would not be ultimately providing that to the jury.
THE COURT: All right.
THE DEPUTY CLERK: It does not go to the jury?
THE COURT: That's correct.
MR. WALLACE: Correct. But we would like to publish.
MR. THOMAS: Yes.
MR. WALLACE: Thank you.
BY MR. WALLACE:
Q. So let's keep moving on, Dr. Guelcher. The article is in

front of the jury, at least the first page is. Can you tell us why you found that article significant?

A. So, this article was interesting because the authors looked at a hundred explants, a hundred meshes removed from human patients, and tried to understand what was happening in terms of the response these materials had on the body.

Q. Could you turn to what would be the fourth page, second column on the right, beginning with the word "analysis"? Do you see that?

A. Yes.

Q. Okay. Do you recall what sort of analysis was done by the authors that conducted this study?

A. Well, they did scanning electron microscopy, or SEM, which is a way for looking at the surface of the material. They did this infrared spectroscopy, which is a way of looking at the chemical groups, chemical bonds on the surface.

Q. What does it mean when it says "uneven way"?

A. Well, "uneven way" would mean that it's -- it's maybe random, it's associated with manufacturing, not other types of responses.

Q. If you could turn to Page 267, please, and look at the area -- the jury has it highlighted in front of them -- talking about the chronic inflammatory reaction. Can you tell us --

A. Yes.

Q. -- whether or not this is at all consistent with your opinions in this case?

A. So, this first paragraph explains the chronic inflammatory reaction, in a way that I was explaining as a foreign-body reaction. So this is free radical synthesis as peroxide, superoxide and hypochlorite. These are all reactive oxygen. They're forms of oxygen that are much more reactive than oxygen that's in the air you breathe. So this would be what I was referring to as reactive oxygen species.

And then the next sentence says, "Once in contact with the polypropylene implant, these radical species could infer oxidation of the carbon-hydrogen bonds." This is what I was explaining earlier. These radical species or reactive oxygen species that are secreted by inflammatory cells, that oxidize that carbon-hydrogen bond. That is what I was explaining earlier.

Q. Do you know -- I'm sorry. Did I interrupt you?

A. No. I'm done.

Q. Do you know where these 100 explants came from, what part of the body?

A. I believe these were pelvic mesh explants, vaginal mesh.

Q. Is there anything else that -- in connection with this study, that -- well, let's just move on to the next article. Why don't we do that.

The Costello article which is 21468, do we have that?

THE COURT: Another learned treatise?

MR. WALLACE: Yes, Your Honor.

THE COURT: All right.

(PLAINTIFFS' EXHIBIT P-21468 WAS RECEIVED IN EVIDENCE.)

BY MR. WALLACE:

Q. Why did you select this article, Dr. Guelcher?

A. Well, this was another article, this is from hernia mesh, but it also explains very clearly how the body can react to implanted polypropylene mesh.

Q. What else, if anything, did you find significant about this article?

A. Well, this article found evidence of surface cracking, just like we saw in the Ethicon studies. There was surface cracking, there was also surface degradation of the material, by spectroscopy, and there was also a change in the molecular weight of the polypropylene that was explanted from these --

THE COURT REPORTER: I'm sorry. The what.

THE WITNESS: The molecular weight -- not the molecular weight. I'm sorry. I spoke incorrectly.

The melting temperatures changing in these, as well.

And so these meshes are showing changes in response to this foreign-body reaction, just like we've seen previously.

BY MR. WALLACE:

Q. If you look at the second page of the article reporting on this study, beginning with the paragraph that says, "As a result of this chronic inflammatory response" --

A. Yes.

Q. -- "the mesh material is exposed to a continuous bath of oxidants."

A. Yes.

Q. Do you see that paragraph?

A. Yes.

Q. Can you tell the jury the significance of this paragraph to your opinions in this case?

A. So this paragraph supports my opinions that this chronic inflammatory response, this is a foreign-body reaction. The mesh material is exposed to a continuous bath of oxidants. Again, these oxidants are reactive oxygen species, more reactive than molecular oxygen, and the mesh is continuously exposed to these materials because the cells are adherent and they secrete these reactive oxygen, and this reaction continues as long as the mesh is there. So these statements are supporting the opinions I --

Q. This study talks about both chemical degradation and physical degradation. What is -- what does that mean in connection -- as it relates to your opinions?

A. Well, chemical degradation would be these changes in the chemical structure of the polypropylene and this degrading,

and, again, these chemical changes can lead to physical changes such as embrittlement and cracking, which is what was observed in this study is these chemical changes lead to physical changes such as cracking in the material.

Q. Let's keep moving, Dr. Guelcher. And you mentioned the Wood article.

MR. WALLACE: Counsel, that would be 21925. Again, another learned treatise, Your Honor.

THE COURT: All right.

(PLAINTIFFS' EXHIBIT P-21925 WAS RECEIVED IN EVIDENCE.)

BY MR. WALLACE:

Q. And, Dr. Guelcher, have you reviewed this study in connection with your work?

A. Yes, I have.

Q. And do you know when it was published?

A. This study was published just last year, 2013.

Q. And what is the significance of this study to you in connection with your opinions in this case?

A. So, what I found interesting about this study is these were three different types of materials that were removed from the same patient, so it gives us a reference for how three different types of materials respond to the foreign-body reaction in the same patient. So it takes out of consideration the patient-to-patient changes.

Q. Do these studies that you've looked at in these three

articles confirm your opinion on degradation?
A. Yes, they do. Again, this study saw evidence of changes in the polypropylene, cracking, changes in the physical properties of the polypropylene over time.
Q. Are these the only three studies that exist in the literature on these issues, Dr. Guelcher?
A. No. There are other studies that have shown this as well, that polypropylene responds to this foreign-body reaction and changes, its chemical properties change and its mechanical structural properties change.
Q. You talked about the less-mesh concept in the summary of your opinions. I'd like us to move to Slide 17, please.
MR. WALLACE: If that's -- before we go there, let's make sure there is no objection.
MR. THOMAS: I just have one of the studies referenced on the slide. Are you going to introduce both studies on the slide?
MR. WALLACE: We're just going to talk about them. I won't introduce them.
MR. THOMAS: I object to the reference to the slide if they're not going to be part of the record in the case.
THE COURT: Just ask the question.
MR. WALLACE: Fair enough.
BY MR. WALLACE:
Q. Have you reviewed the Cobb study regarding lightweight

mesh in hernia repair?
A. Yes, I have.
Q. And have you reviewed that in connection with the opinions that you'd offered on the less-mesh concept?
A. Yes.
Q. Okay. And what, if anything, does the Cobb paper -- or how does the Cobb paper inform your opinions in this case?
A. So, the argument in the Cobb paper is that less mesh is better. And this relates back to my opinions in that if the polypropylene is causing the surface reaction and the polypropylene is responding to that foreign-body reaction and changing, the more polypropylene surface that's present, the greater those changes would be, the more hazardous they could be, and so because of this reaction, the polypropylene in response to the body, it's best to minimize the amount of polypropylene that's present in the mesh. This is the argument that Cobb, et al., are making and is consistent with my opinions.
Q. Have you reviewed the work of Dr. Klinge and Klosterhalfen in the foreign-body reaction to mesh's paper?
A. Yes, I have.
Q. And did that --
MR. THOMAS: Your Honor --
THE COURT: Yes.
MR. THOMAS: That's not sufficiently identified.

There are dozens, as the Court's well aware, of papers between Klinge and Klosterhalfen on different issues.

THE COURT: All right. If you would identify which studies or papers you're talking about.

It's time for our afternoon break, I think, if you're going to be going for a little bit longer.

MR. WALLACE: Actually, no, Your Honor.

THE COURT: Oh, really?

MR. WALLACE: I will be done -- if we take a break, I can probably get organized and get done relatively quickly.

THE COURT: All right. Ladies and gentlemen, we'll take our afternoon break. I'll call you back in 15 minutes.

Don't discuss the case among yourselves. Prevent anyone from discussing it with you or in your presence. I will call you back shortly. Don't use any social media.

COURT SERVICES OFFICER: All rise.

(The jury left the courtroom at 2:30 p.m.)

(The jury entered the courtroom at 2:47 p.m.)

THE COURT: You may resume the stand.

Mr. Wallace.

MR. WALLACE: Thank you. Dr. Guelcher, we're going to proceed.

BY MR. WALLACE:

Q. I want to go back really briefly just to try to finish up to 21925, and that is the Wood article, and the section on

polypropylene on page 1120.

A. Yes.

Q. And I'm going to ask you to look at the words beginning with "unfortunately". And I'll read it for you, Dr. Guelcher. "Unfortunately, polypropylene will degrade in an oxidizing environment such as the environment during a foreign body response. Because of this, polypropylene has been shown to oxidize in vivo. Oxidization of polypropylene results in surface cracking and cracking, changes in mechanical strength and increased brittleness."

Did I read that correctly.

A. Yes.

Q. And what impact, if any, did this Wood article and what I just read have on your opinions in this case?

A. So this Wood article, again, is consistent with my opinion that this oxidizing environment, this is the space between the cell, the cell and the material where we have all this reactive oxygen, that's an oxidizing environment. It says, "such as the environment during the foreign body response." That's the environment I was speaking about. And polypropylene oxidizes in vivo which can cause these changes in chemical composition and also mechanical properties such as brittleness and cracking.

Q. Did you address mechanical failure in your report in this case?

A. I did. I mentioned that these types of chemical changes can result in mechanical failure of the devices as was observed with the pacemaker lead problem.

Q. You gave the jury a few dates about, for example, when foreign body reaction was known and when degradation outside the body was known. Do you know, in connection with reviewing these articles and the work that you've done in the case, when the first study was done to evaluate vaginal mesh implants and the concepts of degradation?

A. Well, the Clavé paper that we were discussing earlier, this Clavé paper was published in 2005, so in 2005 they noted that --

Q. Let's make sure we're looking at the right document. I'm looking at 21457 which was actually a 2010 publication.

A. Yes. Oh, I got the date mixed up. I'm sorry.

21457 is this Clavé study, I was looking at the date wrong.

Q. And are you looking at the conclusion section?

A. I'm looking at the conclusions where they state this is the first study to evaluate synthetic implants used in the vaginal approach.

Q. And have you seen any evidence in the work that you've done in this case or any of the work that you've done with respect to polypropylene that Ethicon has done such research?

A. I've not seen any research from Ethicon in this area, and

again after seeing the degradation of the sutures, as an engineer I would want to know how the Prolene responds to this oxidated environment in the pelvic floor and the mesh, quite different than a suture, but to my knowledge that study has not been done.

Q. In connection with your work, did you have to determine whether or not polypropylene was inert?

A. Yes, I did.

Q. And what did you find?

A. Well, based on the testimony that I provided earlier, I do not believe polypropylene is inert. It is oxidatively unstable, it reacts with oxygen, and its chemical composition changes, so I would not call this an inert material because of its reactivity with oxygen.

Q. Are there any limitations on the use of polypropylene in the pelvis for a permanent implant as it relates to your opinions in this case?

MR. THOMAS: Objection, Your Honor.

THE COURT: Let me see you at sidebar.

(The following occurred at sidebar.)

THE COURT: Mr. Thomas.

MR. THOMAS: Yes, Your Honor. That's an opinion that goes directly to the use of mesh in the pelvic floor which is beyond the scope of his expert report.

MR. WALLACE: Your Honor, I would just say that I

could probably word the question differently and I would go back and just say with respect to his qualifications as a biomedical engineer who's offered his opinions on the case, whether or not as a biomedical engineer there are any limitations with respect to the use of polypropylene inside the pelvis as a biomedical engineer, not a clinical.

THE COURT: I'm not sure you still would have established an adequate foundation even if you asked that, but if you want to try to establish a foundation, I'll let you, but that alone I would sustain the objection.

MR. WALLACE: Okay. If I could ask, and when you speak of foundation, Your Honor --

THE COURT: Well, that is to say as a biomedical engineer, are you familiar with and have you studied chemical composition of the tissues and so forth, and do you have medical training?

MR. WALLACE: Okay. And I'll clarify just so with respect to other witnesses, Your Honor, I will be clarifying that he's not a medical doctor, not offering a clinical opinion.

THE COURT: Yes. Great. Thank you.

MR. WALLACE: Thank you.

(Sidebar concluded.)

MR. WALLACE: Dr. Guelcher, I have just a few more questions.

BY MR. WALLACE:

Q. With respect to polypropylene's use inside the body, a very simple question, are you anti-polypropylene when it comes to using polypropylene in other parts of the body?

A. No, I'm not opposed to the idea of using polypropylene in the body. One of the important definitions about --

MR. THOMAS: Objection, Your Honor. I object to the narrative. He answered the question.

THE COURT: I'll sustain it. He gave a direct answer to the question, so I'll sustain it.

MR. WALLACE: Yes, Your Honor.

If you'll indulge me for one minute, Your Honor.

THE COURT: Certainly.

MR. WALLACE: I have one more thing.

(Discussion was held off the record.)

MR. THOMAS: Your Honor, I expect we're going to need to talk about this.

THE COURT: All right. Excuse us.

(The following occurred at sidebar.)

THE COURT: Mr. Thomas.

MR. THOMAS: Mr. Wallace advises the next exhibit he wants to use with this witness is an instructions for use and I can't imagine what this witness brings. There's nothing about instructions for use in the opinions that he's disclosed in this case.

MR. WALLACE: Do you want me to respond, Your Honor?

THE COURT: Sure.

MR. WALLACE: I understand that he's not a medical doctor. My question is going to be very simple, whether or not he believes that the statement that polypropylene is not subject to degradation is true or false. He's not offering a clinical opinion. I believe he can say as a matter of fact just what he reviewed and we would still be able to, allowed to offer admission of the IFU and those issues. Would that be acceptable, Your Honor?

MR. THOMAS: He's already given his opinion about polypropylene degradation and I think this is inappropriate for this witness.

THE COURT: I'll overrule the objection.

MR. WALLACE: Your Honor, may I publish the document?

THE COURT: You may.

(Sidebar concluded.)

MR. WALLACE: Your Honor, rather than -- I'm sorry, I might have interrupted.

THE COURT: I was going to see if you were going to introduce that.

MR. WALLACE: What I would like to do, so that the next witness can talk about it from a clinical perspective, Your Honor, is that I would use one of my opening slides as just a demonstrative with this witness.

THE COURT: Why don't I just allow you to ask the question again?

MR. WALLACE: Okay.

BY MR. WALLACE:

Q. Let me ask it this way: If the instructions for use that come with this product, the TVT-O product, say that the product does not degrade, is that a true or false statement?

MR. THOMAS: Objection, Your Honor, to the characterization.

THE COURT: Overruled.

THE WITNESS: So what I've spoken about today is the response of the body -- the response of polypropylene to the foreign body reaction.

MR. THOMAS: Objection, Your Honor.

THE COURT: Sustained. Non-responsive.

BY MR. WALLACE:

Q. Can you just answer whether it's true or false?

A. I'm trying to give an explanation.

THE COURT: You can answer it and then give an explanation.

THE WITNESS: Well, last time I tried that I wasn't allowed.

THE COURT: Well, consistency is the hobgoblin of small minds.

THE WITNESS: That's a good one for a professor, I

think.

I don't believe that's true. I believe that I pointed to evidence today that shows that polypropylene reacts in response to a reactive oxygen secreted by the foreign body, by inflammatory cells, by inflammatory cells the polypropylene degrades, its chemical composition changes, it becomes brittle, cracks, and undergoes other changes, and this could have negative effects on a patient's health when implanted in the pelvic floor. So I don't believe --

THE COURT: The jury will disregard last part of the witness's answer.

MR. WALLACE: Thank you, Your Honor.

Let's go to the summary of opinions slide so we can finish, Dr. Guelcher.

THE COURT: I meant the part about his idea that it could have effect on the patient's health. You're to disregard that and not consider it.

I can't answer your questions.

THE DEPUTY CLERK: They want to be able to see the slide.

THE COURT: Oh, the slide coming up. Sure. You're ahead of me. All right.

MR. WALLACE: Thank you, Judge.

BY MR. WALLACE:

Q. With respect to the opinions that you've offered in your

report and your testimony today and this summary of opinions, have you held each of these opinions to a reasonable degree of biomedical engineering and chemical engineering certainty?

A. Yes, I have.

MR. WALLACE: I have no further questions.

THE COURT: Thank you, Mr. Wallace.

Cross examination.

MR. THOMAS: Thank you, Your Honor.

CROSS EXAMINATION OF SCOTT GUELCHER, Ph.D., BY MR. THOMAS:

Q. Dr. Guelcher, how are you today?

A. Good. How are you?

Q. Doctor, you testified on direct that polypropylene is a polymer?

A. Yes.

Q. It was invented in 1950s, correct?

A. Yes.

Q. And when polypropylene was invented, it was very innovative, wasn't it?

A. I mean all materials when they're invented, they're innovative.

Q. Plastics, right? The age of plastics and that was a plastic, correct?

A. Yes, it is a plastic.

Q. Now, Prolene is the brand name for the polypropylene Ethicon uses in its medical devices, correct?

A. Prolene is a brand name, it's essentially polypropylene with antioxidants and lubricants.
Q. And Ethicon first used Prolene in its sutures?
A. That's my understanding.
Q. And sutures are what we in West Virginia call stitches, right?
A. Call them that in Virginia, too, where I grew up.
Q. Down in Blacksburg?
A. Yes, sir.
Q. And so Ethicon Prolene stitches or sutures have been around since the late Sixties?
A. That's my understanding, they've been around since the Sixties.
Q. And what makes Prolene Prolene as opposed to simple polypropylene are the additives that you talked about, correct?
A. Yes. The brand name Prolene is defined by the additives that are added to the polypropylene.
Q. And those additives are calcium stearate, do you remember that?
A. Calcium stearate is added as a lubricant.
Q. And DLTDP because I can't pronounce the full word.
A. It's a long word. It's an antioxidant.
Q. Santonox R?
A. Another antioxidant.

Q. Procol LA-10?
A. I think that's another surfactant.
Q. And a CPC --
THE COURT: That's another what? I didn't hear it.
THE WITNESS: I'm sorry. It's another surfactant or a lubricant.
THE COURT: All right.
BY MR. THOMAS:
Q. And then the coloring, the CPC pigment, correct?
A. Yes, sir.
Q. And those additives are what make Prolene different from the other polypropylene medical devices on the market, correct?
A. There are many different grades of polypropylene; Marlex, Prolene, different grades --
THE COURT: Is that a yes or a no?
THE WITNESS: I'm sorry. Yes.
MR. THOMAS: Thank you.
BY MR. THOMAS:
Q. Now, Ethicon Prolene sutures are what is known as non-absorbable sutures, correct?
A. They're marketed as non-absorbable.
Q. Okay. And what that means is they are supposed to be in the body for life?
A. They're supposed to be without changing, yes.

Q. Do you know where Ethicon gets the polypropylene resin used to make Prolene sutures?
A. My understanding it comes from Sunoco and is compounded in a plant in Kenova on the Kanawha River.
Q. It's made here in West Virginia?
A. Yes, it is.
Q. And it has been since the beginning of the time they made these sutures, correct?
A. My understanding is the plant has changed control, but it's still made in the same plant, it's been bought and sold though.
Q. And you know when Ethicon buys this resin from this plant in Kenova, it actually comes down to Kenova and takes over the plant and makes special runs of the Prolene polypropylene at this plant, correct?
A. I wouldn't agree that they take over the plant. My understanding is that they work with the personnel in the plant to make sure that Ethicon's concerns are addressed during the campaign.
Q. Do you agree that Ethicon personnel thoroughly clean the mixing and compounding equipment before running our Prolene material, Ethicon's Prolene material?
A. You're reading that from a document.
THE COURT: Would you agree with that or not, or do you know?

THE WITNESS: I don't know the level of detail that -- I know that they're there and that they're working. This is a common practice, you work with a sole manufacturer to make sure things are done. I'm speaking on my experience.

THE COURT: Well, Doctor, the important thing here is just listen to the question and try to answer it as asked. He has asked you a question, whether you know -- would you finish it again there, Mr. Thomas?

MR. THOMAS: Your Honor, with the court's permission, I'm going to try to make it a little easier. May I approach the witness?

THE COURT: You may.

BY MR. THOMAS:

Q. Doctor, I'm going to hand you what's been marked as defendant's exhibit 23600. It's a document dated January 23, 2003.

A. Yes.

Q. And it's titled Prolene resin manufacturing specifications.

A. Yes.

Q. You've seen this document before, haven't you?

A. I have seen this document.

Q. And this 2003 document discusses the Prolene manufacturing process in Kenova, West Virginia, doesn't it?

A. Yes, sir, it does.

MR. THOMAS: And Jamie, would you give me the first page of that, please, so the jury can see it?

THE COURT: Do you want to move its admission?

MR. THOMAS: I do, Your Honor. Thank you.

THE COURT: Is there objection?

MR. WALLACE: No, Your Honor.

THE COURT: It may be received and displayed.

(DEFENDANTS' EXHIBIT 23600 WAS RECEIVED IN EVIDENCE.)

MR. THOMAS: Let's go to the first paragraph, Jamie.

BY MR. THOMAS:

Q. Do you recall from reading this document, Mr. Guelcher, that back in the Sixties Ethicon went to a company in New York to try to figure out what kind of polypropylene they were going to use in their Prolene sutures, correct?

A. That's what it says here.

Q. Okay. And they obtained numerous different fiber samples and tested those samples before they chose the one they wanted to use, correct?

A. Yes. It doesn't say how, but it says that.

Q. Okay. And down in the second paragraph it says that Ethicon personnel could go into the plant to insure that the resin was made under proper conditions of cleanliness, etcetera, and to verify that the formulations were as stated on the run sheets. You knew that, didn't you?

A. I'm sorry. What page are you on?

Q. On the front page in the second paragraph, right in the middle.
A. Okay. Mine is organized a little differently. I see. Various deals were struck, Ethicon could go into the plant. That's what I was saying earlier, yes.
Q. Okay. And they bought multi-year supplies at one time, do you remember that from reading the document?
A. What I understand is they would do a campaign every couple years, they would make a lot of material.
Q. So the current practice, end of that paragraph, of week to two week long campaigns every two years, that's how they made their Prolene, correct?
A. That's what it says.
Q. And so you go down to the bottom of the third paragraph. From the beginning of the Sixties, Ethicon has always bought its Prolene from the same plant using the same equipment, with the exception of the polymer reactor, and made by the same people, except for those who have been retired or replaced, correct?
A. That's what it says, yeah.
Q. Now, the second page of that document lists the additives that are in Prolene that we talked about a minute ago, correct?
A. Yes, sir.
Q. And the next paragraph tells about the manufacturing

process for Prolene. And Ethicon insists that the mixing and compounding equipment be thoroughly cleaned prior to running our material. Do you see that? Right under the additives.

A. Under the additives. Yes. I see it.

Q. And Aristech, the owner, and Ethicon inspect the equipment before commencing operations; do you see that?

A. That's what it says.

Q. And once they start the compounding campaign, the first 500 to a thousand pounds that are compounded are discarded as a matter of course; do you see that?

A. That's a fairly common practice, yeah, I understand.

Q. And if the molecular weight of the natural, paren, unpigmented material is acceptable as measured by melt float, we then start collecting material. You know the importance of molecular weight here, don't you?

A. I do, but I don't know what's acceptable means, the specification.

Q. What's the importance of an appropriate molecular weight for polypropylene?

A. Well, the molecular weight has an effect on the properties, but again, it should be within some specification. I don't know what's acceptable --

Q. I didn't ask you that question. I'm asking you about molecular weight. And so it's important to have an appropriate molecular weight for the product before it's

released, you'd agree with that?
A. Molecular weight is typically something we put a specification on.
Q. Okay. And you know this process hasn't changed over the last 50 years?
A. That's what this document says.
Q. Do you have any reason to disagree with that?
A. There were some changes to the formulation, I understand, the antioxidants were changed in the early 1990s. That was changed. The plant actually changed owners I think a number of times.
Q. But the equipment's the same?
A. The facility and the equipment seem to be the same.
Q. Do you have any idea of the uses of polypropylene Prolene sutures in the human body?
A. I know that they're used as sutures for a number of applications.
Q. Do you know whether they come in different sizes?
A. I know that they come in different sizes.
Q. Why do they come in different sizes?
A. Well, I'm not a clinician, but I would assume you'd want different sizes for different types of surgeries that are being done.
Q. Do you know how many Prolene sutures have been implanted in people around the world since the Sixties?

A. That's not a statistic that I'm aware of.
Q. Billions, with a B?
A. Okay.
Q. Do you have any idea whether to disagree with that or not?
A. I said I don't know what the number is. It sounds like it's --
Q. A bunch?
A. It's a lot of hamburgers, yeah.
Q. That's a legal term. I'm sorry. I apologize.

You know from your review of your documents in this case that Ethicon began using Prolene polypropylene in hernia mesh in the mid 1970s, correct?
A. Yes, that's my understanding.
Q. And the, I think you testified that the mesh used in hernia mesh is a bigger piece of mesh, but exactly the same design as that used in TVT, correct?
A. I don't think I said that. I don't think I was comparing hernia to --
Q. Let me ask it this way: Do you know how the Ethicon Prolene hernia mesh compares to the Ethicon Prolene mesh used in TVT?
A. My understanding is that similar mesh is just used in similar products but cut to different shapes, that's my general understanding.

Q. Do you know whether the hernia mesh comes in bigger sheets than the mesh that's in the TVT?
A. I would presume that it would since it's used for a different use than a sling.
Q. And the Prolene used in the hernia mesh is the same chemical composition as the Prolene used in the sutures, correct?
A. It's the same composition, but that doesn't mean it's going to respond the same.
Q. I understand. I just asked you the composition.
A. The composition is the same.
Q. Okay. Do you know how many millions of Prolene polypropylene hernia meshes have been implanted in people around the world since 1975?
A. I assume it's millions and not billions from what you --
THE COURT: I couldn't hear you.
THE WITNESS: I said it sounds like it's millions and not billions. I don't know the number.
BY MR. THOMAS:
Q. Okay. Now, you're aware from your work in this case that Ethicon polypropylene mesh began being used for the treatment of stress urinary incontinence in a TVT mesh in 1996; you know that, don't you?
A. That's correct. To my knowledge.
Q. And the Prolene mesh used for the treatment of stress

urinary incontinence in the TVT mesh is the same chemical composition as the Prolene polypropylene mesh in the hernia mesh, correct?

A. It's all sold as Prolene mesh, so I would assume it has the same composition.

Q. Do you know?

A. It's called Prolene, it's Prolene --

THE COURT: Do you know?

THE WITNESS: Yes. It's the same.

BY MR. THOMAS:

Q. So the Ethicon TVT mesh used for the treatment of stress urinary incontinence is also the same chemical composition as the Prolene suture, correct?

A. It's the same chemical composition.

Q. Do you know how many people have received, around the world, the Prolene mesh for the treatment of stress urinary incontinence?

A. I don't know the exact number. I think it's in the thousands.

Q. Okay. Now, prior to getting involved in litigation of these cases, you had not seen in any of your research that there was a problem with polypropylene mesh, true?

A. I'm not studying in my research, research standard on polypropylene mesh --

Q. Is that true?

A. I think it's true. I'm not aware of any.
Q. Now, prior to your work on these cases, you had never done research on polypropylene as an implantable biomaterial, true?
A. Not researched polypropylene as an implantable biomaterial, but I've --
THE COURT: True or not true?
THE WITNESS: I've not done research on it as an implantable biomaterial.
THE COURT: True or not true?
THE WITNESS: True.
BY MR. THOMAS:
Q. Prior to getting involved in litigation of these cases, you had never published an article on the use of polypropylene in mesh, true?
A. That's true.
Q. And prior to getting involved in this litigation, you had never published any article on polypropylene specifically, true?
A. That's true.
Q. And prior to getting involved in this litigation, you had never given a presentation to any of your colleagues on polypropylene, true?
A. That's true, but I am this fall.
Q. Thank you. And indeed, prior to getting involved in this

litigation, you had not even studied polypropylene, true?
A. No, that's not true. And I know you're going to pull out my deposition on this, but --
MR. THOMAS: Excuse me, Your Honor.
THE COURT: Just wait. Just wait. Not a question pending right now.
THE WITNESS: Yes, sir.
MR. THOMAS: May I approach the witness, Your Honor?
THE COURT: You may.
BY MR. THOMAS:
Q. Now, Dr. Guelcher, you've given depositions in this litigation before, correct?
A. Yes, I have.
Q. And the way depositions work, for the jury, maybe they don't know what a deposition is, you meet with a lawyer in the room and you swear to tell the truth and you answer questions about the litigation before you come in here to testify, correct?
A. That's right.
Q. And when you're asked questions you give truthful answers?
A. I give truthful answers, but sometimes the context of the question can change from the deposition to a trial.
Q. If you'll look at your March 25, 2014 deposition on page 79, line three, and the question is asked -- do you have that?

A. I do.
Q. Okay. And the question is asked at line three, "And you've not studied polypropylene before your work in this case, correct?"
"No. But I've studied oxidating degradation of other polymers?"
Did I read that correctly?
A. You read it correctly, but I think the word studied is vague.
Q. Thank you.
A. He's trying to impeach my testimony. Can I give an explanation? I have one.
THE COURT: Stop. Now. I'm not going to put up with quarrelling from either side. The answer is "no". You've asked me if you may explain your "no" answer. The answer to that is "yes".
THE WITNESS: Thank you, sir. I appreciate it.
THE COURT: Go ahead.
THE WITNESS: I'm sorry for the court.
THE COURT: That's all right. I'm just doing what I do.
THE WITNESS: I understand.
I think the word studied in different contexts can mean different things. I had not done research on polypropylene prior to this litigation. I'm not hiding

anything. But I have taught a course, developed a course on polymer science and engineering at Vanderbilt, I taught it for two semesters, other professors teach it now, and we talked about many types of polymers in this course. So I am familiar with polypropylene, but I do agree that I've not studied it in my research. So it's just this word that I am struggling a little bit with. If you asked me if I've done research, I would say no, I have not, but I have studied and I am aware of the material.

THE COURT: All right. Next question.

MR. THOMAS: Thank you, Your Honor.

BY MR. THOMAS:

Q. Now, you obviously know that Ethicon's TVT mesh is designed to be implanted in the human body?

A. Yes, that's correct.

Q. And you know when those meshes are removed from the human body then they're called an explant?

A. That's what I was explaining earlier.

Q. You have never analyzed a TVT mesh explant manufactured by Ethicon for the treatment of stress urinary incontinence, true?

A. I've not had any explant to --

Q. True?

A. -- characterize, so --

Q. I'm sorry. I don't mean to stop you, but --

THE COURT: I'll take that as an objection as non-responsive. I'll sustain the objection and direct the witness to answer the question as asked.

THE WITNESS: That's true, I've not tested it.

THE COURT: Can I see counsel at sidebar?

(The following occurred at sidebar.)

THE COURT: We're coming close or at least it seems to me to discussing the other mesh cases. I want just to be very sure we don't do that.

MR. THOMAS: I'm trying to tailor my questions to Ethicon specifically, Your Honor.

MR. WALLACE: Just fair warning, he has looked at mesh and you're about to open a can of worms.

THE COURT: He was specific that it was only Ethicon and I'm worried about the witness --

MR. WALLACE: I'm not sure he completely gets where he's going.

THE COURT: Are you going to ask more questions about that, explant testimony?

MR. THOMAS: Just Ethicon specific.

THE COURT: Make it clear that you only want an answer about Ethicon.

MR. THOMAS: Yes, sir.

THE COURT: Just this particular case.

(Sidebar concluded.)

THE COURT: I apologize to Mr. Wallace and Mr. Thomas, to you, Doctor. Proceed.

BY MR. THOMAS:

Q. In fact, Dr. Guelcher, you've never requested to analyze a mesh manufactured by Ethicon for the treatment of stress urinary incontinence, true?

A. Not directly. The company I work for has, I believe.

Q. Do you have your deposition in front of you again?

A. Yes.

Q. Turn to page 21, please, of your March 25 deposition. Are you there?

A. Yes.

Q. "Question: Have you ever requested to analyze a mesh manufactured by Ethicon for the treatment of stress urinary incontinence?"

"Answer: Not to my knowledge."

A. Yes.

Q. Thank you.

A. That's what I said.

Q. I need a little help from --

MR. WALLACE: Your Honor -- go ahead.

Your Honor, there was no impeachment there. I'd just move to just strike the entire questioning from the deposition. It wasn't the question that was asked.

THE COURT: Well, everybody's doing, ladies and

gentlemen, everybody is doing their job as best they see fit. I'll help out a little bit.

If you just answer the question and leave it to the lawyer who called you, if he thinks that something needs further explanation, he'll get back up on redirect and get back into it.

THE WITNESS: I understand.

THE COURT: All right.

MR. WALLACE: Thank you.

THE COURT: You're welcome.

MR. THOMAS: I need some help with the plaintiff's Power Point presentation. Can we go to page seven of the plaintiff's Power Point presentation, please?

BY MR. THOMAS:

Q. Dr. Guelcher, on the direct examination you were talking about, the title is *Oxidation Alters the Structure of Polypropylene*, and what you're explaining there is the chemical reaction between oxygen and polypropylene, correct?

A. That's right.

Q. And when you have oxidation impacting polypropylene, you have a change in molecular structure, don't you?

A. That's right.

Q. And you have a change in molecular weight, don't you?

A. That's right. It happens at the surface layer.

Q. You have a change in molecular weight, didn't you?

A. Yes.
Q. And one of the ways that you measure the extent to which a chemical -- strike that.
One of the ways that you measure the extent to which a substance degrades or oxidizes is by a change in molecular weight, true?
A. That's one way of measuring it, yes.
Q. Okay. And this oxidation that you've described in this chemical structure is also intended to show that the mechanical properties of the product can also change, correct?
A. Well, what's being shown here is just the chemical reaction. I'm not sure what you mean.
Q. But the progression of that is, as you've testified on direct examination, that you ultimately have a change in the physical properties of that substance, correct?
A. Yes.
Q. Like tensile strength, correct?
A. That's true, yes.
Q. Or toughness, correct?
A. Yes.
Q. And so that you can actually measure, by analytical chemistry and benchtop testing, the extent to which a substance has undergone degradation as you've described it in this slide, correct?
A. That's right. That's one way of measuring it.

Q. Now, if you go to the next slide in this set, you're talking about the implant materials selection. This polypropylene, does the polypropylene in this slide, is this Prolene?

A. No, this isn't Prolene; this is polypropylene.

Q. Okay. And we talked about before that Prolene without antioxidants?

A. That's not Prolene.

Q. Exactly.

A. It's polypropylene.

Q. And as you add antioxidants to it, you do so to stabilize the polypropylene, correct?

A. To get the oxidation, yes.

Q. And the reason why you do that is to extend the life of the polypropylene for whatever it's being used for, correct?

A. That's right, yes.

MR. THOMAS: May I approach, Your Honor?

THE COURT: You may.

BY MR. THOMAS:

Q. Now, Dr. Guelcher, I've handed you what's been marked as defendants' exhibit 30884 and this is a 1976 study called *Subcutaneous Implants of Polypropylene Filaments*, first author Liebert, correct?

A. Yes.

Q. And you're familiar with this paper, aren't you?

A. I cited this paper in my report.
Q. And in the Liebert paper, the authors there tested polypropylene without antioxidants against polypropylene with antioxidants, correct?
A. They did, but they were different components, but they did, yes.
Q. Thank you.

And if you go to page two of this exhibit, 3884.2, down at the bottom it says, "The objectives of the study were determined the length of time required for observable degradation to occur, the type of degradation products formed, the rate of degradation, and four, the effect of the presence of an antioxidant on degradation and the rate of degradation."

Do you see that?
A. That's right. That's what it says.
Q. And what the Liebert article found was that there was no oxidation of the polypropylene treated with antioxidants, correct?
A. At 90 days they found that.
Q. Correct?
A. At 90 days, yes.
Q. And at paragraph five on the last page under conclusions, the Liebert group concludes, "Infrared spectra and mechanical testing of implanted and non-implanted filaments containing an antioxidant show no changes in chemical or physical properties

as a result of implantation." Correct?
A. I would agree with that statement up to 90 days.
Q. Thank you.
THE COURT: I'm sorry. You can't agree or disagree? You have a partial agreement, is that right?
THE WITNESS: I have a partial -- I don't know how much -- I don't want to step out of line again. I don't know how much I can say.
THE COURT: All right. Okay.
THE WITNESS: Partial agreement is fair.
BY MR. THOMAS:
Q. Now, you are of the opinion that there is no antioxidant package available that can effectively stabilize polypropylene against the threat of oxidation, correct?
A. I believe that I said the antioxidants are depleted in time, so that they don't last forever. I believe that's what I said.
Q. Do you agree with the statement that I made?
A. Could you read it again?
Q. You are of the opinion that there is no antioxidant package available that can effectively stabilize polypropylene against the threat of oxidation.
A. I don't know of any. I guess I would agree. I don't know of any that would.
Q. And you know what a peer-reviewed study is, don't you?

A. Yes, I've published a lot of peer-reviewed studies.
Q. And a peer-reviewed study is one that somebody writes and subjects to review by your peers before it's published, correct?
A. That's how it works.
Q. And in the 50 years that Prolene polypropylene has been used for implantation in humans, you're not aware of any peer-reviewed study which suggests that Ethicon Prolene loses its antioxidant package such that it oxidizes and becomes embrittled, are you?
A. I've not seen that in a peer-reviewed study.
Q. You don't have an opinion in this case about whether Mrs. Huskey's mesh degraded, do you?
A. I believe it degraded based on the foreign body reaction, but I don't have the data, is that fair?
Q. You don't know whether the mesh is brittle, do you?
A. I've not tested it.
Q. You don't know whether it's oxidized at all, do you?
A. As I said, I believe it is, but I've not tested it because I don't have it.
Q. That's because you don't have the material to test, correct?
A. Yes, sir, that's right.
Q. Let's go to page 10 of the Power Point presentation, please.

Now, you talked to the jury at some length about this flow chart, the effect of the foreign body reaction on implants, and just so it's clear, what you depict here is not your experience with polypropylene, correct?

A. What I show here is based on the experience with the pacemaker lead insulation and what I believe is happening to polypropylene.

MR. THOMAS: Your Honor, move to strike. Ask him to answer the question.

THE COURT: Sustained. The witness is directed to answer the question.

THE WITNESS: Okay. Sorry. What's the question again?

BY MR. THOMAS:

Q. Dr. Guelcher, what you showed here is not related to your experience with polypropylene?

A. Not my experience.

Q. What you show here is your experience with polyether urethane, correct?

A. It's not my experience. It's published experience, yes.

Q. You've not done this analysis, testing it, analyzing it, published it, with respect to polypropylene, have you?

A. No. But I'm in the process of doing that. I'm sorry.

MR. THOMAS: Your Honor, move to strike.

THE COURT: Sustained.

THE WITNESS: I have not done it yet.
BY MR. THOMAS:
Q. Now, you talked about the seven-year dog study. There was no evidence of embrittlement in the sutures tested in the seven-year dog study, do you agree with that?
A. Yes, there was no embrittlement reported in that study.
Q. Thank you.
A. Well, can I qualify it?
Q. And there was no evidence of mechanical breakage in the seven-year dog study, correct?
A. I believe on the surface there was evidence of embrittlement, but what you've asked me --
Q. There's no evidence of mechanical breakage in the seven-year dog study?
A. I do agree that there's no evidence of mechanical breakage.
Q. And no evidence of loss of the mechanical properties of the sutures in the seven-year dog study, do you agree with that?
A. Can I be specific? There was tensile strength, elongation and modulus, and those parameters were not changed. Well, they were changing, but --
THE COURT: Can you answer the question?
A. Those three prongs.
Q. Thank you.

MR. THOMAS: May I approach, Your Honor?

THE COURT: You may.

BY MR. THOMAS:

Q. Dr. Guelcher, I'm handing you what's been marked as defendants' exhibit 23228.

A. Yes.

Q. And 23228 is entitled, *Seven-Year Dog Study*.

A. Yes, I've seen this.

Q. It's a bigger version of what you talked about on direct?

A. Yes, sir.

Q. Has more information than what we talked about on your direct examination, do you realize that?

A. Yes. I've seen the entire study.

Q. And the last three pages of that study are the mechanical properties testing conducted on the mesh after seven years, correct?

A. Yes.

Q. And it's this testing after seven years that showed that the mesh explanted from the dogs after seven years did not lose any of its physical properties, correct?

A. I would not say it does not lose any of its physical properties. They measured strength, elongation and modulus.

Q. For what they tested they didn't lose any of their physical properties, correct?

A. For what they tested.

Q. Is that true?
A. Yes.
Q. Thank you.
And also, if you go to page 115 -- are you at 115?
A. I'm at 115.
Q. Okay. Turn the page briefly. 116 is the area where you testified to the jury about the conclusions, correct?
A. That's right.
Q. And it's conclusions under optical microscopy and scanning electron microscopy, correct?
A. Right.
Q. And those would be visual observations of the test, correct?
A. Well, it's scanning -- it's high magnification, it's visual.
Q. It is visual, correct?
A. It is visual of the surface, yes.
Q. Well, Ethicon also conducted some analytical chemistry on the mesh they explanted from the dogs too, didn't they?
A. They it.
Q. And if you go to page 115, they talk about GPC testing, correct?
A. Yes.
Q. GPC testing is gel permeation chromatography, correct?
A. That's what it stands for.

Q. And gel permeation chromatography measures molecular weight, right?
A. That's right, measures molecular weight.
Q. And what the company found when it measured the molecular weight after of these sutures after 17 years is that there was no significant difference in molecular weight, correct?
A. A couples things. Not 17 years, seven years.
Q. I misspoke. Let me ask the question again so it's clear. Isn't it true that the company reported on October 15, 1992 that the results of the gel permeation chromatography test run on Prolene sutures explanted from dogs after seven years showed no significant difference in molecular weight, correct?
A. That's the way they explain it, but there's not much difference that's given there.
Q. Thank you.
Do you have the Wood article in front of you?
A. Yes, sir, I've got it right here.
Q. Wood?
A. Wood.
Q. The Wood article addressed hernia meshes, correct?
A. Yes, sir.
Q. It doesn't address Prolene polypropylene, does it?
A. It doesn't say Prolene, it says polypropylene.
Q. Okay. The Costello article.
A. Yes.

Q. I'm sorry, I don't have the number in front of me. Do you have the number?
A. Yes. It's 21468.
Q. The Costello article to which you referred on direct, if you go to page two, that's a different mesh company altogether, isn't it? It's a Bard mesh, see under materials and methods?
A. It's a Bard mesh with a polypropylene component.
Q. Okay. But it's not Prolene polypropylene, is it?
A. It's not Prolene.
Q. Now, let's go to the Clavé article. Would you bring that up, please? It's 21457.
If you go to the sixth page of that, under discussion?
A. Yes.
Q. Just the first paragraph under discussion, please.
A. I'm looking for it.
Q. It says, "The primary objectives of this study were to objectively observe a series of prosthetic explants and to characterize potential degradation which may occur in vivo." Correct?
A. That's what it says.
Q. Those are the goals. And they did it by a number of analytical chemistry tests, correct?
A. Yes.
Q. And if you go to the bottom right-hand corner of that

same page, under several hypotheses, last paragraph? Can we blow that up for the jury, please?

"Several hypotheses concerning the degradation of the polypropylene are described below. None of these, particularly direct oxidation, could be confirmed in this study."

Did I read that correctly?

A. You read that correctly. That's the author's opinion.

Q. They're the ones that did the study, correct?

A. That doesn't mean I agree with that statement.

Q. Well, you've not done this study, have you?

A. No, but it's common to see papers --

Q. Okay. Thank you.

THE COURT: I cautioned you about argument. Let's just stop arguing.

THE WITNESS: Okay. Sorry.

BY MR. THOMAS:

Q. Next page, please.

Under direct oxidation of the polypropylene, last sentence.

A. Yes.

Q. FTIR is an analytical chemistry technique where you determine the extent to which there's oxidation in polypropylene, correct?

A. I spoke about that in my direct, yes.

Q. And what you didn't speak about on direct is the last line of that paragraph that says, "The FTIR analysis neither confirmed nor excluded oxidation of polypropylene in the in vivo environment." Correct?

A. Again, I don't share that opinion, but that's what they wrote.

Q. That's what the people who did the testing said, correct?

A. I don't want to argue.

Q. Go to the next page, number eight. And on the right side they're doing DSC analysis, correct?

A. Yes.

Q. And DSC analysis is like a melting point type of analysis so you can determine whether the melting point of a substance changed to determine whether the chemical composition changes, correct?

A. So DSC measures transitions in melting temperature and heat of fusion.

Q. Okay. And you look under in this study, do you see this? "In this study, no difference between DSC thermograms of pristine and degraded samples was found. Additionally FTIR analysis did not conclusively confirm that the degradation was due to oxidation."

Did I read that correctly?

A. The FTIR -- yes, you read it correctly. The FTIR refers to the previous comment.

MR. THOMAS: Your Honor, may I have a moment?
THE COURT: You may.
MR. THOMAS: That's all the questions I have, Your Honor.
THE COURT: Redirect.
MR. WALLACE: Your Honor, may I proceed?
THE COURT: You may.
REDIRECT EXAMINATION OF SCOTT GUELCHER BY MR. WALLACE:
Q. You were asked some questions by Mr. Thomas about the Costello article and the Wood article, and asked whether or not the polypropylene in those articles were Prolene. Do you remember that?
A. Yes, sir.
Q. But you weren't asked by Mr. Thomas about the Clavé article and whether or not there was Prolene in that article.
A. Yes.
Q. Were you?
A. No, I was not.
Q. Can we pull up the images on page 265?
LDPMMF, the one on the right.
A. Yes.
Q. Do you see that?
A. This is not Clavé.
Q. Yes, that's Wood. We'd like to put up Clavé. Let me give you the number. That is 21457.

Dr. Guelcher, just to refresh your recollection, you weren't asked about whether or not this article, the Clavé article, which has a hundred explanted vaginal mesh devices, had any of the polypropylene as Prolene, were you?

A. I was not asked that question.

Q. And isn't it true that in this article Prolene was examined and degradation was found?

THE COURT: Sustained. It is leading. I know it's tempting.

MR. WALLACE: Very tempting, Your Honor.

BY MR. WALLACE:

Q. In examining the Clavé article, did you find that Prolene was a polypropylene mesh that was examined in this study?

A. So on this same page it says the DSC thermograms of treated degraded and non-degraded LDPPMF explants were similar to those of treated Prolene soft. Additionally, the DSC thermograms of degraded --

THE COURT: Could you slow down a bit?

THE WITNESS: I can. Being a professor is hard, you talk too fast.

The DSC thermograms of degraded and non-degraded HDPPMF explant were also similar to those of treated pristine Prolene samples.

Q. Thank you. Let's move on in the article, Doctor. Let's move to page 270 and you'll probably see in your copy there is

some things at the top of the page.
A. Yes.
Q. I'm going to refer you to the left-hand column beginning with the word polypropylene that's already highlighted. If you could highlight down to the bottom of the column there.
A. Yes.
Q. And I ask if you could read that first paragraph, please, and tell me whether or not Mr. Thomas asked you about that paragraph.
A. "Polypropylene, in particular, LDPPMF, is the most used material in the PFD surgery. It is generally considered an inert material. This study contradicts this established fact and confirms the results of other studies on polypropylene materials used in other areas of medical specialization."

I was not asked about this paragraph.

Q. And with respect to the LDPPMF, is that what was referred to as the Prolene?
A. From the previous page that I read, yes.
Q. Thank you.

And you were asked now -- well, you were asked about Clavé, Wood and Costello. Did each of those studies confirm degradation?

MR. THOMAS: Objection, Your Honor. Asked and answered. Beyond the scope.

THE COURT: I'm going to allow it. And it's leading.

But I want to get.

THE WITNESS: In my direct examination I testified that those papers point to degradation either through surface cracking, changes in other types of properties. In my opinion they all point to degradation.

BY MR. WALLACE:

Q. Did Mr. Thomas present you with one study that says --

THE COURT: Let's don't do argumentative stuff.

MR. WALLACE: I'm sorry, Your Honor.

Q. Did Mr. Thomas present you with any studies that say pelvic floor mesh does not degrade?

A. He did not present me with any studies and I've not seen any studies that state that.

Q. You were asked some questions about embrittlement on cross examination. In your review of Ethicon documents, did you see whether or not Ethicon did any research on its meshes whatsoever for embrittlement?

A. I've not seen the studies in the meshes. The sutures studies did point to embrittlement on the surface. And it starts at the surface --

MR. THOMAS: Your Honor, object. It's non-responsive.

THE COURT: First part of the answer is directly to the question and may be considered by you. When the doctor started going on, you're to ignore that.

THE WITNESS: My students do that, too.
BY MR. WALLACE:
Q. As a biomedical engineer that's offered opinions in this case and the evidence you've reviewed and your experience working on polypropylene mesh, do you think it's important for a medical device manufacturer to test for embrittlement before putting polypropylene mesh into women?
MR. THOMAS: Objection, Your Honor. Beyond the scope.
THE COURT: I sustain it as beyond the scope.
BY MR. WALLACE:
Q. You were asked some questions about a plant at the beginning of your cross examination. Do you recall that line of questioning?
A. Yes, I do.
Q. Whether or not there's a clean plant, does that affect your opinions in this case?
A. No. It just tells me that there's a reproducible way to manufacture the material, that it's not changed.
Q. Does clean polypropylene degrade?
A. All polypropylene degrades.
Q. Have you -- you were asked some questions about your experience with vaginal mesh. Have you given any scientific presentations on vaginal mesh failures at any scientific conferences?

MR. THOMAS: Your Honor, I'm --

THE COURT: Can I see counsel?

(The following occurred at sidebar.)

THE COURT: Let me just shortcut this. I don't recall him being asked about his experience with vaginal mesh.

MR. WALLACE: Sure. He was asked about his experience with researching polypropylene and the work done in this case. All I was simply pointing out is that he's been asked to present at conferences regarding his research. So if I phrase the question differently, I could do that and just move on.

THE COURT: I don't quite know what you're doing.

MR. THOMAS: Your Honor, that's really getting into the area that we're trying to avoid because if he has any research at all, it's not in this case, it's in the other cases. And if I'm going to cross examine him at all -- and just for court's benefit, I know for a fact that he and his co-expert, Dr. Dunn, have conducted extensive analytical testing on other meshes. I could have gone into that at great length because he didn't do the same kind of testing here, and it's the same kind of issue. That's the kind of research that he's doing that they're presenting at these conferences and I just don't want to get into this.

THE COURT: Okay. Don't get us into a mess.

MR. WALLACE: Okay. I'll be very careful.

(Sidebar concluded.)

BY MR. WALLACE:

Q. Dr. Guelcher, I'm going to ask a very simple yes or no question and I just want you to answer it yes or no without an explanation.

Have you given any presentations to scientific peers on the failure of vaginal mesh?

A. Have I given any? No.

Q. Well, let me ask, I'm going to give you your CV and ask if I can refresh your recollection.

THE COURT: Yes, sir.

MR. THOMAS: I'll let him ask the question first.

BY MR. WALLACE:

Q. I'm going to direct you to page 18 of your CV, page 153. I'd ask that you don't say anything else other than whether or not you've given a presentation to scientific communities about the failure of vaginal mesh.

MR. THOMAS: Your Honor, asked and answered. The question is whether it refreshes his recollection.

THE COURT: I'll let him answer.

THE WITNESS: I'd like to explain my answer.

THE COURT: No.

THE WITNESS: It's --

THE COURT: No. Honestly, we're almost finished here -- go ahead.

THE WITNESS: I'm trying to do this the right way.
BY MR. WALLACE:
Q. Can you just answer yes or no? Have you ever given a presentation or gone or been invited to any conferences to speak on that issue?
THE COURT: I overrule your objection. He may impeach his own witness.
THE WITNESS: But there's a very simple 15-second explanation.
THE COURT: I am telling you, if you don't answer this question directly, you're excused.
THE WITNESS: No.
BY MR. WALLACE:
Q. You were asked some questions -- I've just got a couple more questions. You were asked some questions about FTIR tests and whether or not they could find degradation.
A. Yes.
Q. Are there limits to FTIR testing and whether or not that's a valid way to find degradation?
A. FTIR probes, it measures the sample surface and also the interior, so you're typically measuring the entire volume and not specifically what happens at the surface.
THE COURT: So I bet that's a yes.
THE WITNESS: Yes.
BY MR. WALLACE:

Q. Have any of Mr. Thomas's questions changed your opinion in this case?

A. No.

MR. WALLACE: Thank you.

THE COURT: All right. May the witness be excused from the trial? Or do you want him --

MR. THOMAS: Yes, Your Honor.

MR. WALLACE: Yes, sir.

THE COURT: All right. Thank you very much, Doctor.

Call your next witness.

Doing all right, ladies and gentlemen? All right.

MR. WALLACE: We're going to play the video deposition of Brigette Helhammer, Your Honor.

THE COURT: Ladies and gentlemen, the next testimony you will be presented with is by way of video deposition. As you've already heard from the lawyers, a deposition is sworn testimony. This particular testimony is taken and is done so under oath and you are to consider it as offered to you just the same as if that witness was sitting here today live. You're to give it no greater weight or no lesser weight because it's on TV.

You may proceed.

MR. WALLACE: Thank you, Your Honor.

(The video testimony of Brigette Helhammer was played.)

MR. KUNTZ: Judge, that concludes the deposition of Brigette Helhammer.

THE COURT: All right. Call your next witness.

MR. COMBS: Judge, there will be a very short defense cross examination.

THE COURT: Okay. Well, let's do that.

(The video testimony of Brigitte Helhammer continued.)

MR. KUNTZ: Short redirect.

THE COURT: Redirect.

(The video testimony of Brigitte Helhammer continued.)

THE COURT: All right. Thank you.

Ladies and gentlemen of the jury, that concludes the videotaped testimony of this witness. You are to consider that testimony the same way you would as if the witness were here testifying. As to the technical quality of the video, I want to assure you that the lighting technician has been hired by Steven Spielberg and will not be available for later work.

Call your next witness.

MR. KUNTZ: Plaintiffs call Dr. Bruce Rosenzweig.

**BRUCE A. ROSENZWEIG**, called as a witness, having been first duly sworn according to law, testified as follows:

DIRECT EXAMINATION OF BRUCE A. ROSENZWEIG BY MR. KUNTZ:

Q. Please state your name for the record.

A. Bruce Alan Rosenzweig.
Q. And are you a physician?
A. Yes, I am.
Q. What kind of doctor are you?
A. My specialty is gynecology and my subspecialty is urogynecology.
Q. Please describe to the jury your medical training and experience.
A. I went to the University of Michigan for medical school. After that I did a postgraduate residency program in obstetrics and gynecology. Following that -- which is a four year residency. I spent one year after that doing what's called a pelvic surgery fellowship, which is an advanced pelvic surgery. And then I did a two-year fellowship in urogynecology.
Q. Are you licensed to practice medicine?
A. Yes, sir.
Q. What states?
A. I have an active license in the state of Illinois.
Q. What teaching positions have you held?
A. Currently I'm an assistant professor at in obstetrics and gynecology at Rush University Medical Center.
Q. Have you published any articles related to the treatment of stress urinary incontinence?
A. Yes, I have.

Q. Okay. Have you published any articles related to the pelvic floor?
A. Yes, I have.
Q. Have you presented lectures on stress urinary incontinence?
A. Yes, I have.
Q. About how many lectures have you presented?
A. I've presented several hundred lectures, probably the majority of those have to do with urinary incontinence or pelvic floor.
Q. Please describe to the jury your current practice in urogynecology and the treatment of stress urinary incontinence.
A. Well, I see patients in the office two days a week and I operate a day and a half a week, and then I have other responsibilities.
Q. How many times do you perform surgery a week?
A. A day and a half, sir.
Q. Do you remove pelvic mesh products during your surgeries?
A. Yes, I do.
Q. And how many pelvic mesh products do you think you've removed in your career?
A. Over 250.
Q. And how many of those products were sling products that you've removed?

A. Approximately 75 percent, or about 200.
Q. And how many of those sling products that you removed were products made by Ethicon?
A. Probably about 40 to 50.
Q. And how about actual sling products by Ethicon that you have removed from your patients?
A. That's about 40 or 50 Ethicon sling products.
Q. Do those include the TVT products?
A. That is correct.
Q. The TVT Retropubic?
A. That is correct.
Q. And the TVT-O?
A. That is correct.
Q. How do you know when you're removing them that they're Ethicon products?
A. Well, a lot of times I have the operative report. It's always good to see before you operate on a patient what procedure they had, what kind of material they had. Also, the TVT products are blue which makes it easier to see and distinguish in the operating room.

MR. KUNTZ: May I approach the witness, Your Honor?

THE COURT: You may.

BY MR. KUNTZ:
Q. I'm going to hand you what's been marked exhibit 90003A. Tell the jury what that document is, doctor?

A. This is my curriculum vitae. It is kind of your calling card, your resumé of the things that you've done throughout your career.

Q. Okay. Does this accurately reflect the things that we just discussed, your experience, your training and your practice?

A. That is correct.

MR. KUNTZ: Your Honor, I would move to qualify Dr. Rosenzweig as a witness and move to admit his CV.

THE COURT: Any voir dire?

MS. JONES: Not at this time, Your Honor.

THE COURT: Doctor, you may answer opinion questions placed to you in your area of expertise.

THE WITNESS: Yes.

MR. KUNTZ: I apologize, Your Honor, but I'd also move to admit his CV.

THE COURT: Is there objection?

MS. JONES: I have no objection, Your Honor.

THE COURT: It may be received.

(THE PLAINTIFFS' EXHIBIT WAS RECEIVED IN EVIDENCE.)

BY MR. KUNTZ:

Q. Dr. Rosenzweig, when did we first contact you to review this case?

A. Approximately the fall of 2013.

Q. And did we ask you to form opinions about the TVT-O

device?
A. That is correct.
Q. What materials have you reviewed in this case to form your opinions?
A. I've reviewed the literature, I've reviewed internal documents, and I've reviewed deposition testimony of medical directors, scientists and also other Ethicon corporate witnesses.
Q. How much have you charged for your time in Jo Huskey's case?
A. Approximately 50 to $70,000, that's at $500 an hour for reviewing materials.
Q. And are you charging for your time here to be at trial here today?
A. That is correct. I'm charging $5,000 a day to be here at trial.
Q. And how do you determine that rate, Dr. Rosenzweig?
A. Well, I have a private practice; not only am I responsible for paying my own salary, but my employees' salary. I pay for the rent, their health insurance, other overhead for my practice, and so that rate is to, to take care of my time away from practice to compensate me for my time away from my practice.
Q. How much time have you spent reviewing documents in this case?

A. Between 120 and 140 hours.
Q. Talk a little bit -- let me ask you this. Your practice obviously involves treating patients for stress urinary incontinence?
A. That is correct.
Q. We've heard a little bit about it, but what is stress urinary incontinence?
A. Well, stress urinary incontinence is a medical condition whereby a woman will actually lose her urine during activities such as coughing, sneezing or other things that increase the pressure inside the abdomen.
Q. Is it a life-threatening condition?
A. No, but it can be embarrassing. It can be also a social or a hygienic problem.
Q. What percentage of stress urinary incidence is severe?
A. Well, it's been estimated only about 10 percent of stress urinary incontinence is severe, and by severe we mean leaking more than one time a day.
Q. And what are the different surgical options to treat stress urinary incontinence?
A. There are three basic procedures. One is called the Burch procedure, one is called the pubovaginal sling procedure, and the final category is called the midurethral sling procedure.
Q. I'm going to pull up a slide of the different SUI

treatment options. It there's no objection, Your Honor.

MS. JONES: I have no objection to the use of the demonstrative.

THE COURT: You may display.

BY MR. KUNTZ:

Q. Slide one. Dr. Rosenzweig, if you could kind of walk the jury through the three different procedures that you have done or that you recognize for the treatment of stress urinary incontinence.

A. Yes. The first is called the Burch procedure. That is a procedure that is done either with a telescope called a laparoscope or through a small incision that's done above the pubic bone. The pubic bone is basically the bone that your belt buckle sits on.

You go into the area above the internal organs of the abdomen. The abdomen is covered by, if you will, a cellophane wrapping which protects the bowel and the other internal organs from any kind of injury from rubbing together. So you go down to that layer which is sitting right next to the bladder, and two stitches are placed on each side of the opening of the bladder, which is called the bladder neck, and the area where the urethra, which is the tube that you pee out of, comes out of the bladder. Those are brought up to a strong ligament on the inside of the pubic bone, which is called the Cooper's ligament, and the sutures are tied.

The pubovaginal sling is an operation where a material, usually it is something like a strip of fascia -- fascia is a substance that is like a tendon or a ligament. It's made out of collagen, so it is fairly strong. And this is placed either through the vagina or through an incision at the level of the opening of the bladder, which is called the bladder neck, and brought up through the muscles that is called the rectus muscle. That's your abdominal muscles that you try to strengthen while doing sit-ups.

The final is the midurethral sling which is a technique by which a piece of polypropylene in a tape-like fashion is placed at the level of the midpart of the urethra and either brought up above the pubic bone or out through the inner thigh.

Q. Have you performed all three of these procedures?

A. Yes, I have.

Q. Have you performed the TVT-O procedure that's at issue in this case?

A. Yes, I have.

Q. Have you performed the TVT procedure, the predecessor product to the TVT-O?

A. That is correct.

Q. In total in your career how many surgical procedures of all types combined to treat stress urinary incontinence have you performed?

A. Over 1600.
Q. Which surgery do you normally do or do you prefer for the treatment of stress urinary incontinence?
A. I perform the Burch procedure.
Q. And how many Burch procedures have you performed?
A. Over 1200.
Q. How long has the Burch procedure been around?
A. Since about the mid Sixties.
Q. Is it still recognized as a standard of care?
A. That is correct.
Q. Is it still recognized by AGOS, the AUA and other physician society groups?
A. That is correct.
Q. And you've explained the procedure to us a little bit. How big is the incision for a Burch procedure?
A. Well, normally if I'm just doing this as a standalone procedure, I can get by with a fairly small incision, maybe four inches. If I'm doing it with a hysterectomy or another surgical procedure, the incision might be a little bit bigger. Obviously there might be some anatomical variation where the patient might be a little bit larger, then I would have to like make a slightly bigger incision.
Q. How long do you patients normally stay in the hospital after a Burch procedure?
A. Usually overnight, occasionally two days.

Q. Is there literature of a course where patients stay longer after Burch procedures?
A. Yes. But in my practice I don't see the necessity to do that.
Q. Is there any mesh involved in a Burch procedure?
A. No. It's using sutures instead of a woven mesh.
Q. In all of the literature you've reviewed, we're going to discuss some of it, between the Burch and the TVT-O procedure, were they both effective at the same rates?
A. That is correct.
Q. Is there literature that shows that the two procedures are equivalent?
A. Yes. There have been approximately three long-term, meaning five year, randomized control trials. A randomized control trial means that patients are randomly assigned to get one procedure or the other, and then the patient has the procedure, and then they're followed up for a period of time, and in these studies it's up to five years. And there was found to be no difference in the success rate between the procedures.
Q. In your experience, in your practice and the literature you've reviewed, do you see long-term complications with Burch?
A. I have not experienced a significant number of long-term complications. I rarely see any long-term complications from

my Burch procedure.
Q. What do you define as long-term?
A. Well, short-term is following up someone for one to two years, long-term, five to ten years is what is standardly considered short-term and long-term.
Q. How long do you consider post operative pain to be?
A. Well, normally when a patient comes in to have a surgical procedure, they understand that they're going to have some pain right after surgery from making the cut or we're doing some procedure on an organ, there's going to be some discomfort afterwards as the area that was operated on heals. Normally it can be as short as a few weeks or as long as four to six weeks.
Q. And is post operative pain something you see with every operation?
A. That is correct.
Q. And is that very different than long-term chronic pain?
A. That is correct.
Q. In your practice doing I think you said over a thousand Burch procedures, you've never seen a patient with long-term pain?
A. I can't remember any. There have probably been less than a handful.
Q. You've testified that you've used both TVT Retropubic and TVT Obturator products, is that correct?

A. That is correct.
Q. Explain to the jury a little bit -- first tell them what the TVT Retropubic device is and when it came out.
A. Yes. The Retropubic TVT, as we talked before, comes with the piece of tape, the polypropylene, it's placed through the vagina and the ends come out above the pubic bone through the abdominal wall, through the incision in the skin. This was created in the mid Nineties.

And the other technique is known as the trans -- should I move on to the transobturator?
Q. Right.
A. The transobturator technique is the other technique, what we're talking about in this case, are where again an incision is made in the vagina and the polypropylene tape is brought out through the inner thigh.
Q. Before you ever implanted slings, did you have a concern about them?
A. That is correct.
Q. Did you discuss those concerns with anybody?

THE COURT: Excuse me.

MS. JONES: I'm sorry. I apologize, Counsel. I'm having a hard time when you back away.

BY MR. KUNTZ:
Q. Prior to the time you ever implanted a sling, did you have concerns about them?

MS. JONES: Objection, Your Honor.

THE COURT: Sustained.

BY MR. KUNTZ:

Q. When's the first time that you implanted --

THE COURT: Would you turn his microphone up a little bit?

THE DEPUTY CLERK: I can't.

THE COURT: Would you speak a little louder? I'm having trouble too, I thought it was just my age.

MR. KUNTZ: I will, Your Honor. I apologize.

BY MR. KUNTZ:

Q. When's the first time that you implanted a TVT?

A. In 2003.

Q. When is the first time that you implanted the TVT-O that's at issue in this case?

A. Well, I had the opportunity to go to Belgium --

MS. JONES: Objection, Your Honor. Non-responsive.

THE COURT: Sustained. If you'll just answer his question.

THE WITNESS: Yes. In October of 2004.

THE COURT: There you go.

BY MR. KUNTZ:

Q. Were you invited by Ethicon to attend one of their training sessions?

A. That is correct.

Q. And when was that?
A. October of 2004.
Q. And where did that training take place?
A. In Liege, Belgium.
Q. And did that training with the TVT-O take place with Dr. de Leval, the inventor of the product?
A. That is correct.
Q. And you were invited by Ethicon and they paid for you to go over to Belgium and train with Dr. de Leval?
A. That is also correct.
Q. Tell us a little bit about that training class over in Belgium.
A. Well, it was a three-day course. The first day was in a classroom where we had didactic lectures. The second day we spent in a cadaver laboratory where we got to do dissections to show the area where the tape was going to go anatomically, and also on a cadaver actually place the tape. And then the third day we spent in the operating room with Dr. de Leval and I had the opportunity of placing the tape in two live patients.

THE COURT: All right. It's five o'clock. I'm quite certain this witness will take more than just a few more minutes. We're going to recess for the day.

Thank you, Doctor, you may step down.

Ladies and gentlemen of the jury, that concludes the

testimony for today. We will -- you can go ahead, Doctor.

We'll start again in the morning right at 9:00 o'clock. I appreciate your promptness. We'll begin on time. I missed it by ten minutes this morning, I'm not going to miss it tomorrow.

Very important. Don't watch TV, local news, don't read the newspaper, local newspaper. You can read the New York Times or something like that. You can watch the national news. If you want to stay happy, just don't watch the news, it's depressing.

You're not to listen to, read anything about, see anything, do any research about, use any social media, talk to anyone about, answer any questions about this case. Everything that you're allowed to do about this case you're allowed to do right in here. Don't discuss it with anyone or among yourselves. Have a very pleasant evening and I'll see you right at 9:00 o'clock.

You're excused.

Counsel, do you want to stay a minute?

(The Jury left the courtroom at 5:02 p.m.)

THE COURT: Anything you need me for?

I appreciate the nice professional relationship between counsel and the way this is going. Keep it up. See you tomorrow morning.

MR. KUNTZ: Thank you, Your Honor.

(A recess was taken at 5:03 p.m.)

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**REPORTERS' CERTIFICATE**

**Carol Farrell, CRR, RMR, CCP, RPR,** Official Court Reporter of the United States District Court for the Southern District of West Virginia, and **Anthony Rolland, CRR, RMR, RPR,** do hereby certify that the foregoing is a true and accurate transcript, to the best of our ability, of the proceedings as taken stenographically by and before us at the time, place, and on the date hereinbefore set forth.

**/S/ Carol Farrell, CRR, RMR, CCP, RPR** **08/25/2014**
**Court Reporter** **Date**

**/S/ Anthony Rolland, CRR, RMR, RPR** **08/25/2014**
**Court Reporter** **Date**

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